

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

MYCO INDUSTRIES, INC.,

Plaintiff/Counter-
Defendant,

v.

Case No. 2:19-cv-10645
Hon. Gershwin A. Drain

BLEPHEX, LLC,

Defendant/Counter-
Plaintiff,

v.

JOHN R. CHOATE,

Counter-Defendant,

v.

JAMES RYNERSON,

Defendant.

**OPINION AND ORDER REGARDING CLAIM CONSTRUCTION AND
SETTING TELEPHONIC SCHEDULING CONFERENCE FOR JUNE 10,
2020 AT 10:00 A.M.**

I. INTRODUCTION

On March 4, 2019, Plaintiff Myco Industries, Inc. (“Myco”), brought this declaratory judgment action against Defendant BlephEx, LLC (“BlephEx”),

seeking a declaratory judgment that it has not, and is not directly, indirectly, or contributorily infringing United States patent number 9,039,718 (“‘718 Patent”), as well as seeking a declaratory judgment that the claims of the ‘718 Patent are invalid under 35 U.S.C. §§ 102, 103 and/or 112. On June 7, 2019, BlephEx filed Counterclaims against Myco and Defendant John R. Choate alleging direct and indirect patent infringement and unfair competition under § 43(a) of the Lanham Act and Michigan common law.

This matter is before the Court for claim construction. A hearing was held on May 29, 2020.

II. FACTUAL BACKGROUND

The ‘718 patent discloses “[a] method and apparatus for treating ocular disorders such as blepharitis, meibomitis, and dry eye syndrome.” ECF No. 68, PageID.3283. The specification explains that prior art methods of treating such ocular disorders included instructing patients to clean the affected area at home, however such methods were inadequate because patients “routinely fail to totally cleanse the margin of the eyelid, the base of the eyelashes, and the meibomian glands.” *Id.* at PageID.3287. Thus, the goal of the ‘718 Patent was to create a method and apparatus for use in treating these ocular disorders that addresses patients’ failure to adequately cleanse the affected area. *Id.*

The application for the ‘718 Patent initially received a non-final rejection of the claims over the Grenon prior art reference. An Examiner interview was held where the applicant explained his invention was not limited to contacting the outer surface of the eyelids, rather it contacts the “inner surface of the eyelid or eyelid margin.” *Id.* at PageID.3616. The applicant submitted amendments to the claims, including in Claim 1 a limitation that “the swab ha[s] at least a portion thereof configured to access an inner edge portion of the eyelid margin.” *Id.* at PageID.3743. The applicant also added new claims, which issued as Claim 15 and Claim 17, both of which included a limitation directed to “contacting the inner edge portion of the eyelid margin with the swab.” *Id.* at PageID.3745.

On March 11, 2015, the Examiner issued a Notice of Allowance, which included the Examiner’s Amendment adding the limitation “between the eyelashes and the inner edge of the eyelid margin.” *Id.* at PageID.3811. Applicant agreed to the amendment and the ‘718 Patent issued.

The ‘718 Patent has only two independent claims, Claims 1 and 17. The ‘718 Patent also has dependent Claims 14 and 15, which play an important role in the construction of Claim 1. These Claims state, with the dispute terms in bold:

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 removeable debris** with the swab thereby impacting the debris with the swab to remove debris from the eye.

* * *

14. The method of claim 1 further comprising: accessing at least **an inner edge portion of the eyelid margin** with the swab.

15. The method of claim 14 further comprising: **contacting the inner edge portion of the eyelid margin** with the swab.

* * *

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

effecting movement of the swab relative to the electromechanical device;

while the swab is being moved by the electromechanical device, contacting at least an inner edge portion of the eyelid margin that includes the removeable debris with the swab thereby impacting the debris with the swab to remove debris from the eye.

ECF No. 68, PageID.3290.

In 2017, an entity named MiBo Medical unsuccessfully challenged the validity of the ‘718 Patent in *Inter Partes* Review (“IPR”). On February 28, 2018,

the Patent Trial and Appeal Board (“PTAB”) issued a final decision finding all claims of the ‘718 Patent valid.

III. LAW & ANALYSIS

A. Standard of Review for Claim Construction

Claim construction is an issue of law. *See Markman v. West View Instruments, Inc.*, 517 U.S. 370, 388-90 (1996). Claim terms “are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art.” *Thorner v. Sony Comp. Entm’t Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). It is the claims that measure the invention. *SRI Int’l . Matsushita Elec. Corp.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985). “There are only two exceptions to this general rule: 1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution.” *Id.*

In *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005), the Federal Circuit provided guidance on the hierarchy of evidentiary sources for claim construction. First, “the claims themselves provide substantial guidance as to the meaning of particular terms.” *Id.* at 1314. Second, the claims “must be read in view of the specification.” *Id.* Third, a court “should also consider the patent’s prosecution history, if it is in evidence.” *Id.* at 1317. The claims, specification, and prosecution history are “intrinsic evidence” and are the favored sources for

claim construction. *Id.* Courts may also look to extrinsic evidence, though such evidence “is less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Id.* (quotation marks omitted).

Claim construction always begins with the language of the claim and asks “how a person of ordinary skill in the art understands a claim term.” *Id.* at 1317-18; 1224. A “person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the dispute term appears, but in the context of the entire patent, including the specification.” *Id.* at 1313.

B. Disputed Terms

1. “Eyelid Margin” (Claims 1, 17)

Myco’s Proposed Construction	BlephEx’s Proposed Construction
No construction needed	“the edge of an eyelid, which is divided into an anterior portion and a posterior portion by the physiological feature of the gray line”

Myco argues that the Court should not construe the claim term “eyelid margin.” Myco asserts that BlephEx’s proposed construction goes too far and creates ambiguity because it adds the concepts of an anterior portion and a posterior portion. ECF No. 67, PageID.2420. Myco maintains that the experts agree Figures 2A and 2B of the ‘718 Patent show the upper eyelid margin (60) and the lower eyelid margin (62). *Id.* As such, Myco argues that the jury can see the drawings, which plainly show the two eyelid margins.

Myco complains that the terms anterior portion and posterior portion do not appear in the '718 Patent, thus these terms would have no meaning to the jury and are unnecessary to the jury's understanding of what part of the eye is the eyelid margin. Myco further argues that BlephEx's construction creates ambiguity because it adds the word "edge" to the claims, however this word is not defined in the '718 Patent. Myco asserts that adoption of BlephEx's construction would make the claims very confusing for the jury.

Contrary to Myco's argument, construction of this claim term is necessary because a juror may not readily understand the meaning of the term "eyelid margin." Thus, construing this claim will assist the trier of fact. *See, e.g., Markman*, 52 F.3d at 979 ("[I]n a case tried to a jury, the court has the power and obligation to construe as a matter of law the meaning of language used in the patent claim."). Myco's position that the terms "anterior portion" and "posterior portion" are unnecessary is directly contrary to Myco's argument made in support of its request for injunctive relief, wherein Myco based its non-infringement argument on the distinction between the "anterior" and "posterior" portions of the eyelid margin. Myco's assertion that construing this term is unnecessary appears disingenuous.

As to the proposed construction of "eyelid margin," Myco's expert, Dr. Steve Silberberg, agreed with BlephEx's expert, Dr. Penny Asbell, who explains

that this term refers to “the edge of an eyelid, which is divided into an anterior portion and a posterior portion by the physiological feature of the gray line.” ECF No. 72, Ex. 2 ¶ 80. BlephEx’s proposed construction is consistent with the use of the term “eyelid margin” in the specification. For instance, Figure 2A shows the “eyelid margin of an eye” being cleaned. *Id.*, Ex. 1 at 3:28-31. A review of this figure reveals that the upper and lower eyelid margins include the gray line dividing the margin into an anterior portion and posterior portion. *Id.*

Based on the foregoing, the Court will construe the claim term “eyelid margin” to mean “the edge of an eyelid, which is divided into an anterior portion and a posterior portion by the physiological feature of the gray line.”

2. “An inner edge portion of the eyelid margin” (Claims 1, 17)

Myco’s Proposed Construction	BlephEx’s Proposed Construction
Indefinite	“the portion of the eyelid margin posterior to the gray line”

Myco argues that the claim terms “inner edge portion of the eyelid margin” are indefinite. Patents are presumed to be valid. 35 U.S.C. § 282(a). A party asserting indefiniteness—which is a form of invalidity—bears the “burden of proving indefiniteness by clear and convincing evidence.” *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017). A patent claim is invalid for indefiniteness only if the claim, read in light of the intrinsic evidence “fail[s] to

inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014).

Myco’s argument that the term “inner edge portion of the eyelid margin” is indefinite is without merit. As an initial matter, the Examiner suggested adding the term “inner edge of the eyelid margin” to Claim 1 via an Examiner’s amendment. ECF No. 68, PageID.3811. The Federal Circuit has explained, “we presume that an examiner would not introduce an indefinite term into a claim” because it is “presumed that public officials do their assigned jobs.” *Tinnus Enter., LLC v. Telebrands Corp.*, 733 F. App’x 1011, 1020 (Fed. Cir. 2018) (quoting *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 939 (Fed. Cir. 1990)). Myco fails to explain how it has overcome this presumption. Nor does Myco provide any authority wherein a court has found a claim term introduced by an Examiner to be indefinite.

When the Examiner suggested the addition of “inner edge of the eyelid margin” to Claim 1, the Examiner identified where in the specification a POSA would find support for this limitation, specifically by identifying Figures 2A and 2B as showing “the device contacting the eye between the eyelashes 64 and the inner edge of the eyelid margins, 60, 62.” Moreover, the parties’ experts agree that POSAs understand what the eyelid margin is and what its boundaries are. Indeed, Myco’s expert circled the eyelid margin in his declaration. ECF No. 68-5, ¶ 25.

Myco argues that “inner edge” is indefinite because there is purportedly no precise point where the eyelid margin transitions to the conjunctiva. However, it is well settled that “[t]he definiteness requirement . . . mandates clarity, while recognizing that absolute precision is unattainable.” *Nautilus*, 572 U.S. at 910. The prosecution history directly supports BlephEx’s proposed construction, including the PTAB’s 2018 decision and the WO 2012/092320 prior art reference (“‘320 Reference”) illustrating eyelid anatomy. *See V-Formation, Inc. v. Bennetton Grp. SpA*, 401 F.3d 1307, 1311 (Fed. Cir. 2005) (“[P]rior art cited in a patent or cited in the prosecution history of the patent constitutes intrinsic evidence.”)

The PTAB’s February 28, 2018 decision credited BlephEx’s expert’s testimony 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.” ECF No. 68, PageID.3952. The PTAB expressly referred to the portion of the eyelid margin posterior to the gray line as the “inner (posterior) eyelid margin.” *Id.* at 3950-51. Consistent with the PTAB’s explanation, the ‘320 Reference also shows that the eyelid margin is divided by the gray line (40) into a posterior eyelid margin (38) and an anterior eyelid margin (36). *Id.*, Ex. 7.

Based on the foregoing, the Court will reject Myco’s indefiniteness argument and will construe “an inner edge portion of the eyelid margin” to mean “the portion of the eyelid margin posterior to the gray line.”

3. “A portion of the eye between the eyelashes and the inner edge of the eyelid margin” (Claim 1)

Myco’s Proposed Construction	BlephEx’s Proposed Construction
Indefinite as to “inner edge of the eyelid margin” “between” means the area bounded by but not including the eyelashes or the inner edge of the eyelid margin	“a portion of the eye from the base of the eyelashes to the edge of the eyelid margin that contacts the eyeball”

The parties’ dispute with respect to this claim term appears to be whether the “base of the eyelashes” is included within the area “between the eyelashes and the inner edge of the eyelid margin.” Myco argues that BlephEx’s expert agrees with Myco’s construction because she has opined that “[t]o the extent Myco’s contention is that the eyelashes themselves – i.e., the hairs (keratin) – and the inner edge itself are not ‘between the eyelashes and the inner edge of the eyelid margin,’ I do not disagree with this understanding.” ECF No. 67, PageID.3024. Myco complains that Dr. Asbell agrees that the area “between” the two endpoints does not include those endpoints, but she and BlephEx are making the “artificial” distinction that the “base of the eyelashes” is not a part of the eyelashes.

BlephEx counters that Myco’s contention that “base of the eyelashes” includes the eyelash hair below the surface of the eyelid margin is incorrect in light

of the specification. The specification does not disclose an ability to go under a patient's eyelid margin skin to clear the lash follicles. According to BlephEx, read in the context of the specification, "base of the eyelashes" means the skin around the eyelash hair that can be cleaned with the swab. BlephEx further asserts that the '718 Patent's specification makes clear that "base of the eyelashes" is included in the area "between the eyelashes and the inner edge of the eyelid margin." Indeed, the very problem the '718 Patent seeks to address is that patients "routinely fail to totally cleanse the margin of the eyelid, the base of the eyelashes, and the meibomian glands." ECF No. 68, PageID.3287. As such, BlephEx argues there is no basis upon which to construe the claim terms in such a manner that the device would not serve the very purpose it was intended to serve. *See, e.g., Apple Comp. v. Articulate Sys., Inc.*, 234 F.3d 14, 25 (Fed. Cir. 2000) (noting that it is appropriate to consider the "purpose of the invention" during claim construction). Finally, BlephEx notes that Myco's expert, Dr. Silberberg appears to agree that the "base of the eyelashes" is "where the eyelashes are growing out of the anterior eyelid margin." ECF No. 68, PageID.3524.

Based on the foregoing, the Court will construe "a portion of the eye between the eyelashes and the inner edge of the eyelid margin" to mean "a portion of the eye from the base of the eyelashes to the edge of the eyelid margin that contacts the eyeball."

**4. “configured to access an inner edge portion of the eyelid margin”
(Claim 1)**

Myco’s Proposed Construction	BlephEx’s Proposed Construction
Indefinite as “inner edge portion of the eyelid margin” “configured to” means specifically designed and manufactured to	“safe for accessing the portion of the eyelid margin posterior to the gray line”

Myco argues that the ‘718 Patent uses the term “configured to” as “designed and manufactured to” based on the patent’s specification. For example, the ‘718 Patent states that “the electric motor 30, the chuck 32, and the control switch 34 are integrated into the body 28 so that the electromechanical device 10 is configured to be handheld as shown in FIG. 1.” ECF No. 68, PageID.3288. Thus, Myco contends that the ‘718 Patent explains that the phrase “configured to” means that the electromechanical device is designed to be handheld as it is depicted in Figure 1. Additionally, Myco notes that the specification states “[i]t will be appreciated that any known control switch 34 or plurality of control switches 34 may be configured to power the device 10 on and off.” *Id.* at PageID.3289. Here again, the ‘718 Patent’s specification uses “configured to” to explain that the control switch is designed to power the device on and off.

Conversely, BlephEx argues that a POSA would understand “configured to” to mean “safe for” based on the intrinsic evidence. BlephEx directs the Court to the specification, which states that the swab which contacts the eyelid margin “may

be manufactured of any material suitable for contacting the eye 15 without harming the eye 15” such as a medical grade sponge. ECF No. 68, PageID.3288. Thus, BlephEx argues that a POSA would understand it is important that the swab for the invention be “configured to” or “safe for” touching the inner edge portion of the eyelid margin because the swab could contact the eyeball. BlephEx further maintains that the prosecution history supports its construction because the Applicant amended Claim 1 to recite the “configured to” limitation to overcome the Grenon reference, because “Grenon fails to describe any portion of the heat sink 46 capable of accessing an inner edge portion of the eyelid margin.” As such, BlephEx maintains “configured to” is directed to what the device is capable of (safe for) touching, not what it must actually touch (which is the contacting limitation). ECF No. 72, PageID.4612.

Based on the foregoing, the Court will reject BlephEx’s proposed construction and construe “configured to” to mean “designed to” access an inner edge portion of the eyelid margin. Other courts have held that the plain and ordinary meaning of “configured to” means “designed to.” *See Smart Trike USA, LLC v. Ofrat Baby Toys Mfgs. Ltd.*, No. 10-2063, *3 (D.N.J. Nov. 17, 2011) (construing “configured to” to mean “designed and manufactured to”); *In re Certain Earpiece Devices*, No. 337-TA-912, *16 (I.T.C. Aug. 21, 2014)

(construing “configured to” in the patent to have its plain and ordinary meaning of “designed to, shaped to, or constructed to.”).

5. “contacting a portion of the eye between the eyelashes and the inner edge of the eyelid margin that includes the removable debris” (Claim 1)

Myco’s Proposed Construction	BlephEx’s Proposed Construction
Indefinite as to “inner edge portion of the eyelid margin”	“contacting a portion of the eye from the base of the eyelashes to the edge of the eyelid margin that contacts the eyeball that includes the removable debris”
“contacting” means purposefully touching	
“between” means the area bounded by but not including the eyelashes or the inner edge of the eyelid margin	

Myco argues that the term “contacting” means “purposefully touching.” Myco asserts that the specification describes that the swab’s method may include “scrubbing, exfoliating, or buffing.” Thus, these are all procedures that require more than an accidental contact.

BlephEx argues that “contacting” is a simple term understood by all, thus it does not require construction. BlephEx complains that Myco’s attempt to require “purposefully” touching has no basis in the intrinsic evidence. The Court agrees that “contacting” does not require construction because it is a simple, easily understood term.

Based on the foregoing, the Court finds “contacting a portion of the eye between the eyelashes and the inner edge of the eyelid margin that includes the removable debris” requires no construction.

6. “contacting the inner edge portion of the eyelid margin” (Claim 15)

Myco’s Proposed Construction	BlephEx’s Proposed Construction
Indefinite as to “inner edge portion of the eyelid margin”	“contacting the portion of the eyelid margin posterior to the gray line”
“contacting” means purposefully touching	

Similar to the discussion for “contacting a portion of the eye between the eyelashes and the inner edge of the eyelid margin that includes the removable debris,” the claim terms “contacting the inner edge portion of the eyelid margin” also require no construction.

IV. CONCLUSION

Accordingly, for the reasons articulated above, the Court concludes that with respect to the ‘718 Patent;

The term “eyelid margin” means “the edge of an eyelid, which is divided into an anterior portion and a posterior portion by the physiological feature of the gray line.”

The term “an inner edge portion of the eyelid margin” means “the portion of the eyelid margin posterior to the gray line.”

The term “a portion of the eye between the eyelashes and the inner edge of the eyelid margin” means “a portion of the eye from the base of the eyelashes to the edge of the eyelid margin that contacts the eyeball.”

The term “configured to access an inner edge portion of the eyelid margin” means “designed to access an inner edge portion of the eyelid margin.”

The term “contacting a portion of the eye between the eyelashes and the inner edge of the eyelid margin that includes the removable debris” requires no construction.

The term “contacting the inner edge portion of the eyelid margin” requires no construction.

The Court will hold a Telephonic Scheduling Conference on Wednesday, June 10, 2020 at 10:00 a.m.

SO ORDERED.

Dated: June 3, 2020

/s/Gershwin A. Drain
GERSHWIN A. DRAIN
United States District Judge

CERTIFICATE OF SERVICE

Copies of this Order were served upon attorneys of record on June 3, 2020, by electronic and/or ordinary mail.

/s/ Teresa McGovern
Case Manager