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#### UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MICHIGAN

Myco Industries, Inc.,

Plaintiff,

v.

Case No. 2:19-cv-10645-GAD-EAS

Blephex, LLC,

Defendant.

JURY TRIAL DEMANDED

### AMENDED PLAINTIFF MYCO INDUSTRIES INC.'S MOTION FOR PRELIMINARY INJUNCTION AND BRIEF IN SUPPORT

#### **MOTION**

Myco Industries, Inc. moves for a preliminary injunction to enjoin Blephex, its officers, agents, and those in active concert with it, from making baseless allegations of patent infringement and from threatening litigation against Myco's potential customers. The grounds for this motion are detailed in the Brief, below.

Pursuant to Rule 7.1(a), Myco attempted to ascertain whether this motion would be opposed. Despite reasonable efforts, including a phone conversation with opposing counsel and several email exchanges with opposing counsel, Myco was unable was unable to conduct a conference.

#### BRIEF IN SUPPORT

#### **CONCISE STATEMENT OF ISSUES PRESENTED**

1. Whether the Court should enjoin defendant Blephex, its officers, agents, and those in active concert with it, from making baseless allegations of patent infringement and from threatening litigation against Myco's potential customers where Plaintiff Myco is not directly or indirectly infringing Blephex's patent and where the customers (medical practitioners) are immune from suit.

2. Whether the Court should enjoin defendant Blephex, its officers, agents, and those in active concert with it, from making baseless allegations of patent infringement and from threatening litigation against Myco's potential customers where Blephex violated the Lanham Act by competing unfairly with Myco.

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#### **CONTROLLING AUTHORITY**

Certified Restoration Dry Cleaning Network, L.L.C. v. Tenke Corp., 511 F.3d 535 (6th Cir. 2007)

15 U.S.C. §1125(a)(1)(B) 35 U.S.C. § 271 35 U.S.C. § 287(c)



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### **Other Authorities**

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#### I. INTRODUCTION

Myco developed and recently began marketing a tool—AB Max—that medical professionals can use to treat an eye condition called anterior blepharitis. At a trade show in February, Blephex's founder, James Rynerson, approached Myco's chairman, John Choate, and accused him of infringing Blephex's (only) patent. Dr. Rynerson also threatened Myco's potential customer with litigation if it bought an AB Max.

Blephex's patent can only be infringed by using it to treat *posterior* blepharitis. Myco has never infringed the patent because Myco, which is not in the medical profession, has not used AB Max to treat posterior blepharitis. In addition, Myco offers and sells AB Max only for the treatment of *anterior* blepharitis, which use cannot infringe the Blephex patent. Blephex and Dr. Rynerson know that the patent is limited and that Myco is not infringing. Their accusations of patent infringement made to Myco and its potential customers were objectively baseless and improper.

In addition, as Blephex and Dr. Rynerson know, medical practitioners— Myco's only potential customers—are immune from liability if they would use AB Max to treat posterior blepharitis (contrary to Myco's instructions). Because of that immunity, Blephex cannot sue Myco's potential customers for infringement of the Blephex patent. Therefore, Blephex and Dr. Rynerson's accusations of patent infringement made to Myco's potential customers were objectively baseless and improper.

Myco is likely to succeed on its declaratory judgment claims of noninfringement and Lanham Act violations. If Blephex is not enjoined, Myco will suffer loss of customers, which may be irreparable. Blephex suffers no hardship if it cannot make baseless accusations of patent infringement; in contrast Myco suffers if Blephex makes such accusations and loses customers. Finally, the public interest in free and open competition weighs in Myco's favor. The Court should enjoin Blephex, its officers, agents, and those in active concert with it, from making their baseless allegations of patent infringement and from threatening litigation against Myco's potential customers.

#### II. BACKGROUND

### A. Myco's AB Max anterior blepharitis tool

Myco has been designing, developing, and manufacturing ophthalmic and optometric devices since 1993. Led by Chairman John Choate, Myco also repairs/rebuilds ophthalmic and optometric devices and instruments, and aids others in the development and manufacture of such devices and instruments.

The Myco product at issue in this lawsuit is called AB Max. AB Max is an FDA registered device for use by medical practitioners. AB Max is not a standalone device. It is an attachment for an AlgerBrush II handle, which is made by The Alger Companies, not Myco. (Ex. 1, Choate Decl., ¶ 3.) AlgerBrush II, according to The Alger Companies' web site, is "used by ophthalmologists, ER physicians and, [*sic*] optometrists who are trained and licensed to remove foreign bodies from the eye of a patient." (*See* Ex. 2, p. 2.) Among other things, the AB Max, when used with the AlgerBrush II, enables the tip to rotate forward and in reverse and includes a patent-pending pulse feature. (Ex. 1 at  $\P$  3.)

Myco markets the AB Max attachment solely to treat *anterior* blepharitis (hence the initials "AB" in the name). Blepharitis is a condition characterized by inflammation of the eyelids and the formation of dandruff-like scales on the eyelashes. (Ex. 3, MacGill, "Blepharitis and how to treat it," *Medical News Today*, p. 3 (Jan. 5, 2018)). The medical profession recognizes two forms of blepharitis: anterior and posterior. (*Id.*) "Anterior blepharitis affects the front edge of the eyelid, where the eyelashes join it." (*Id.*) "Posterior blepharitis affects the inner edge of the eyelid." (*Id.*)

Myco has never promoted or marketed the tool for use in treating posterior blepharitis. (*See, e.g.*, Ex. 1 at  $\P$  6; Ex. 4.)

#### B. Background of the '718 patent

In July 2012, ophthalmologist James Rynerson, M.D., filed U.S. Application No. 13/556,729 ("the '729 application") with the United States Patent and Trademark Office ("PTO") for a "method and device for treating ocular disorder." As detailed below, before it would allow the patent to issue, the PTO made Dr. Rynerson expressly limit his patent claims to treatment of posterior blepharitis. The patent issued to Blephex<sup>1</sup> on May 26, 2015 as U.S. Patent No. 9,039,718 B2 ("the '718 patent"). (Ex. 5.)

When Dr. Rynerson filed the '729 application, the claims included both process ("method") and machine ("device") claims. (Ex. 6, File History at 151.) The PTO required Dr. Rynerson to choose which statutory category<sup>2</sup> of claims it wanted to pursue in the patent application and Dr. Rynerson chose the process claims. (*Id.* at 151-52.)

As filed, Dr. Rynerson's process claims covered both anterior and posterior blepharitis treatment. This is as-filed Claim 1:

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

<sup>&</sup>lt;sup>1</sup> During the pendency of the application, its ownership changed hands twice. In July 2013, Dr. Rynerson assigned ownership of the application to Rysurg, LLC, a company Dr. Rynerson co-owned with Mr. Choate (as explained *infra*). In August 2014, Rysurg, LLC assigned it to the current owner, Blephex, LLC, a company for which Dr. Rynerson acts as Chief Executive Officer ("CEO"). For simplicity, throughout the Brief Myco refers to the patent owner as Blephex even though, at some points, a predecessor in interest owned the rights to the patent application.

<sup>&</sup>lt;sup>2</sup> The patent statute defines four categories of patentable subject matter: "process, machine, manufacture, [and] composition of matter." 35 U.S.C. § 101. Dr. Rynerson's originally filed claims fell into two of the four categories (process and device), so the PTO required him to limit the claims of the '713 patent to either a process or a device.

effecting movement of the swab relative to the electromechanical device;

while the swab is being moved by the electromechanical device, contacting a portion of the eye that includes the removable debris with the swab thereby impacting the debris with the swab to remove debris from the eye.

(*Id.* at 11.) This claim describes "contacting a portion of the eye that includes the removable debris" and does not limit the treatment to just the inner eyelid margin (posterior blepharitis) as the issued patent's claims do.

The PTO searched for prior inventions similar to the process claimed by Dr. Rynerson and found a published patent application, U.S. Pat. Pub. No. 2007/0060988, naming Grenon as an inventor ("Grenon"). The PTO found that Grenon anticipated Dr. Rynerson's as-filed claims under 35 U.S.C. § 102(b). (*Id.* at 153-56.)

Dr. Rynerson's attorney then called the PTO examiner who was examining the patent application. (*Id.* at 177-78.) According to the written summary of the interview, Dr. Rynerson's attorney and the examiner discussed Grenon, specifically focusing on "the inner surface of the eyelid or eyelid margin" to differentiate Dr. Rynerson's process from Grenon. (*Id.* at 178.)

Dr. Rynerson then amended the pending claims to add the following limitation (underlined):

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;

(Id. at 181, underlining in original.)

Dr. Rynerson also added a new independent claim 29:

29. (New) 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;

while the swab is being moved by the electromechanical device, *contacting at least an inner edge portion 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.

(*Id.* at 183, emphasis added.)

In Remarks that accompanied these changes, Dr. Rynerson confirmed that what made his invention patentable in view of Grenon was "contacting an inner edge portion of an eyelid margin." (*Id.* at 186.) Dr. Rynerson told the PTO that it had "amended claims 1-4 and added new claims 27 and 28 in accordance with the agreement reached during this interview." (*Id.*) Dr. Rynerson also told the PTO that the newly limited claims had support in the specification and drawings because "FIG. 2A . . . shows a swab accessing and contacting an inner edge portion of an eyelid margin." (*Id.*)

The PTO was still not satisfied that Claim 1 was limited enough to be patentable over Grenon. (*Id.* at 195.) In a phone call with Dr. Rynerson's attorney, the examiner suggested that Dr. Rynerson add the phrase "contacting at least an inner edge portion of the eyelid margin" to Claim 1, making Claim 1 consistent with claim 29. (*Id.*) Dr. Rynerson's attorney said he would consider the suggestion. (*Id.*) In a follow-up phone call, Dr. Rynerson's attorney authorized the examiner to add the following limitation to Claim 1: "between the eyelashes and the inner edge of the eyelid margin" (*Id.* at 249) to distinguish Dr. Rynerson's invention from Grenon's earlier invention. Once Dr. Rynerson had limited all claims to treatment of just the inner eyelid area—*i.e.*, treatment of posterior blepharitis only—the PTO allowed the patent to issue. (*Id.* at 291.)

#### C. The Choate–Rynerson partnership

Shortly after filing the application that became the '718 patent, Dr. Rynerson began exploring how to commercialize his treatment method. Dr. Rynerson was referred to and sought out Mr. Choate. (Ex. 1 at  $\P$  8.) In October 2012, Mr. Choate and Dr. Rynerson met and eventually entered into a partnership in which Mr. Choate agreed to use his skills and knowledge about medical devices and how to manufacture them to make Dr. Rynerson's concept a reality. (*Id.*) Mr. Choate and Dr. Rynerson then jointly formed Rysurg, LLC ("Rysurg") in Michigan, with the agreement that Mr. Choate would be paid an annual salary as well as a

percentage of company profits. (*Id.* at  $\P$  9.) Mr. Choate would additionally serve as President of Rysurg. (*Id.*) The Rysurg, LLC operating agreement, executed on March 1, 2013, referred to a Rysurg, LLC Employment Agreement for Mr. Choate that Dr. Rynerson refused to execute. (*Id.* at  $\P$  10.) That Employment Agreement, had it been executed, included a non-compete obligation that ended in 2017. (*Id.*)

During their partnership, Mr. Choate modified Dr. Rynerson's device design, developed a prototype, and oversaw the manufacture and commercialization of the final product. (*Id.* at  $\P$  11.) The final product consisted of a handpiece with a removable tip that rotates in forward and reverse directions to remove debris from the eyelid via the '718 method. (*Id.*) The device was named the "Blephex" and Mr. Choate and Dr. Rynerson brought it to market in June 2013. (*Id.*)

Mr. Choate was employed by and served as President of Rysurg from December 2012 until January 2014. (*Id.* at  $\P$  9.) During that time, Mr. Choate (and his wife Carol Ann Bristen-Choate) ran Rysurg company operations from Myco's office in Michigan and managed billings. (*Id.* at  $\P$  12.) Despite Dr. Rynerson's obligations to pay Mr. Choate and his wife for their work for Rysurg, those payments were not made. (*Id.*) In January 2014, Mr. Choate was compelled to end his relationship with Dr. Rynerson and file suit against Rysurg and Dr. Rynerson to recover wages Dr. Rynerson had failed to pay Mr. Choate for his work in managing Rysurg and the Blephex business. (*Id.*) After years of contentious litigation (that included counterclaims and a separate lawsuit by Dr. Rynerson against Mr. Choate and Myco), Dr. Rynerson paid Mr. Choate \$162,000 in settlement of their disputes. (*Id.* at  $\P$  13.)

### D. Dr. Rynerson's objectively baseless threats and bad faith allegations of patent infringement

Myco began marketing its AB Max tool in 2019. Given the nature of their respective businesses, which includes marketing products to optometrists, Mr. Choate and Dr. Rynerson attend common events, including trade shows. This year, both attended and hosted booths at the Southern Educational Congress of Optometry ("SECO") 2019 trade show in New Orleans, Louisiana from February 20–24. (*Id.* at ¶ 14.) The annual SECO conference enables companies to promote and display their goods and services to over 6000 optometric professionals from around the world. (Ex. 7.) SECO 2019 organizers report that "[m]ore than 70% of SECO attendees make buying decisions or recommend purchases for their practice" and "55% of attendees make purchases onsite or within 1 year of attending SECO." (*Id.*)

At SECO 2019, Myco launched the AB Max tool. At the Myco booth, Mr. Choate showed the AB Max tool and handed out materials to optometrists explaining its functionality and use. (Ex. 1 at  $\P$  16.) Myco has never promoted or marketed the tool for use in treating posterior blepharitis, only for treating anterior

blepharitis. (*See e.g.* Ex. 1 at  $\P\P$  6, 16; Ex. 4.) The AB Max retail price is less than one-third of the Blephex and other competitive devices. (Ex. 1 at  $\P$  7.)

As discussed above, to get his patent allowed, Dr. Rynerson had to limit his claims to the treatment of posterior blepharitis only. Nevertheless, during the SECO 2019 conference Dr. Rynerson approached the Myco booth and became hostile and combative stating that the AB Max infringes Dr. Rynerson's patent. (*Id.* at ¶ 17.) Dr. Rynerson made the false accusation loudly and within earshot of prospective customers, while videoing at least part of the encounter on a cell Dr. Rynerson knew, or should have known, that his patent is phone. (Id.)infringed only if a medical professional treats posterior blepharitis, which Myco was not doing at the SECO 2019 show and has never done. (Id. at  $\P$  6, 16.) Moreover, he knew, or should have known, that treating anterior blepharitis cannot infringe his '718 patent because of the limits he placed on the patent to get it allowed. Dr. Rynerson's very public allegations of patent infringement were therefore objectively baseless and made in bad faith.

During the exchange, Dr. Rynerson pointed to a plastic model depicting an eyelid afflicted with blepharitis that was displayed at Myco's booth as evidence of the supposed infringement. (*Id.* at ¶ 18.) The plastic model does not and cannot infringe the '718 patent because it is not a tool for treating posterior blepharitis. Myco uses the model merely to show what blepharitis looks like. (*Id.*) Dr.

Rynerson complained that the Myco model looked like the one Blephex uses. (*Id.*) As Dr. Rynerson knows, however, Mr. Choate designed and fabricated a blepharitis model during their Rysurg partnership, without compensation by Dr. Rynerson, and Mr. Choate owns the rights to the custom Myco model. (*Id.*) In any event, the model is not evidence of infringement, which can only occur if a medical practitioner actually treats posterior blepharitis.

In addition to his disruptive behavior at the Myco booth, Adam Farkas, MD, later overheard Dr. Rynerson at the Blephex booth repeating his false claims to Myco's potential customers. Dr. Farkas is the founder of an optometrist educational forum and continuing education platform ODwire and CEwire. Dr. Rynerson told optometrists (potential Myco customers), who mentioned Myco's AB Max, that Myco was "totally infringing on his patents' and that he'd be 'taking action.'" (Ex. 8.) However, as a physician, Dr. Rynerson is or should be aware that, medical practitioners are immune from infringing a method patent when performing a medical activity, such as treating blepharitis. *See* 35 U.S.C. §287(c) (discussed in § IV.A.3, below.)

Dr. Rynerson made accusations of patent infringement by Myco that he knows to be false and he threatened potential Myco customers with lawsuits knowing that those customers, medical practitioners, are immune from suit. Dr. Rynerson is improperly interfering with Myco's sales of AB Max devices and seeking to tarnish the reputation and goodwill Myco has built over more than 25 years.

Mr. Choate plans to attend and host a Myco booth at the Vision Expo East conference in New York on March  $21^{st}$  through March  $24^{th}$ . (Ex. 1 at ¶ 20.) Mr. Choate is understandably concerned that Dr. Rynerson's harassment, disparagement, and threats against Myco and prospective customers will continue at the Vision Expo East conference (as well as future conferences and trade shows for optometrists and physicians) if the Court does not enjoin Blephex and Dr. Rynerson. Therefore, Myco asks the Court to enter a preliminary injunction prohibiting Blephex (including Dr. Rynerson) from (1) making false allegations that the AB Max infringes the '718 patent, and (2) making baseless threats to sue physicians and optometrists that purchase and/or use the AB Max.

#### III. LEGAL STANDARD

When deciding a motion for preliminary injunction, a court must consider four factors: "(1) whether the movant has a strong likelihood of success on the merits; (2) whether the movant would suffer irreparable injury without the injunction; (3) whether issuance of a preliminary injunction would cause substantial harm to others; and (4) whether the public interest would be served by the issuance of the injunction." *Certified Restoration Dry Cleaning Network, L.L.C. v. Tenke Corp.*, 511 F.3d 535, 542 (6th Cir. 2007). These factors must to be balanced; they are not prerequisites to be met. *Id.* Because a preliminary injunction

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is only intended "to preserve the relative positions of the parties until a trial on the merits can be held," such relief "is customarily granted on the basis of procedures that are less formal and evidence that is less complete than in a trial on the merits." *Id.* 

Each of the factors weighs in favor of granting Myco's motion for preliminary injunction.

#### IV. MYCO IS ENTITLED TO A PRELIMINARY INJUNCTION

# A. Likelihood of success: Blephex cannot meet its burden to prove that Myco infringes the '718 patent

Blephex, as the patent owner, has the burden to prove infringement by a preponderance of the evidence. 35 U.S.C. § 271;<sup>3</sup> *Siemens Med. Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, 637 F.3d 1269, 1279 (Fed. Cir. 2011) ("Patent infringement . . . is an issue of fact, which the patentee must prove by a preponderance of the evidence."). Blephex cannot meet that burden. Myco has not directly infringed the '718 patent, nor has it indirectly infringed the '718 patent by inducing others to infringe or contributorily infringing. In addition, medical practitioners who perform a medical activity using Myco's AB Max anterior blepharitis tool are immune from infringement. 35 U.S.C. § 287(c).

<sup>&</sup>lt;sup>3</sup> The pre-AIA version of the Patent Statute governs the '718 patent because the patent was filed on July 24, 2012 (Ex. 5, cover), before the America Invents Act took effect on March 16, 2013. (Pub. Law 112–29, 125 Stat. 293 § 3(n)(1).)

# 1. Myco does not directly infringe under § 271(a) because Myco does not use or perform the infringing method

The '718 patent is a "process" patent because it includes only method claims. (Ex. 5, Claims 1-17.) A person directly infringes a method claim under 35 U.S.C. § 271(a) only by performing the claimed method. Ricoh Co. v. Quanta Computer Inc., 550 F.3d 1325, 1333 (Fed. Cir. 2008) ("Infringement of a method claim occurs when a party performs all of the steps of the process . . . .") (citations and internal quotation marks omitted). The sale or offer for sale of a *product* does not and cannot infringe a method claim—only performance of the claimed method infringes. NTP, Inc. v. Research In Motion, Ltd., 418 F.3d 1282, 1317 (Fed. Cir. 2005) ("Under section 271(a), the concept of 'use' of a patented method or process is fundamentally different from the use of a patented system or device."); Joy Techs., Inc. v. Flakt, Inc., 6 F.3d 770, 774 (Fed. Cir. 1993) ("[A] method claim is not directly infringed by the sale of an apparatus . . . . The sale of the apparatus is not a sale of the method.").

As explained earlier, the medical profession recognizes two forms of blepharitis: anterior and posterior. (Ex. 3, MacGill, "Blepharitis and how to treat it," *Medical News Today*, p. 3 (Jan. 5, 2018)). "Anterior blepharitis affects the front edge of the eyelid, where the eyelashes join it." (*Id.*) "Posterior blepharitis affects the inner edge of the eyelid." (*Id.*)

During prosecution of the application for the '718 patent, Dr. Rynerson expressly limited the patent claims to a method of treating *posterior* blepharitis. Every claim includes the limitation that treatment must occur "between the eyelashes and the inner edge of the eyelid margin" (Ex. 5, Claims 1-16) or "an inner edge portion of the eyelid margin" (*Id.*, Claim 17).

To prove direct infringement under § 271(a), Blephex must show that Myco has used AB Max in a process that includes all limitations of at least one claim of the '718 patent. *Aristocrat Techs. Austl. PTY Ltd. v. Int'l Game Tech.*, 709 F.3d 1348, 1362 (Fed. Cir. 2013) ("To establish liability for direct infringement of a claimed method or process under 35 U.S.C. § 271(a), a patentee must prove that each and every step of the method or process was performed."). The '718 patent process requires "treating an eye for an ocular disorder" and, in particular, treating the "inner edge of the eyelid margin." (Ex. 5, Claims 1-17.) Myco has never used AB Max to treat any "ocular disorder," let alone the "inner edge of the eyelid margin." (Ex. 1 at  $\P$  6.) Yet, Dr. Rynerson, Blephex's CEO, accused Myco of infringing the '718 patent at Myco's sales booth on February 21, 2019—an objectively baseless allegation.

In addition, Blephex has no evidence that Myco has used AB Max as required by the patent claims. As detailed above, the claims of the '718 patent are infringed only when treating posterior blepharitis. Myco has never used AB Max

in this way (Id. at  $\P$  6), and Blephex has no proof of such use.

Blephex cannot meet its burden to show that Myco directly infringes the '718 patent under § 271(a).

#### 2. Myco does not infringe indirectly under §§ 271(b) or (c) because Myco has not induced infringement and because AB Max does not contributorily infringe the '718 patent

## a. Blephex cannot prove active inducement under § 271(b)

To prove active inducement under § 271(b), Blephex must show that Myco actively induced, promoted, encouraged, or influenced use of AB Max in a way that would infringe the patent claims, *i.e.*, to treat posterior blepharitis. *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1331 (Fed. Cir. 2016) ("The Supreme Court has explained that the term 'induce' as it is used in § 271(b) 'means "[t]o lean on; to influence; to prevail on; to move by persuasion."") (alteration in original) (citations omitted); *DSU Med. Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1304 (Fed. Cir. 2006) (*en banc* as to Section III.B.) ("The plaintiff has the burden of showing that the alleged infringer's actions induced infringing acts and that he knew or should have known his actions would induce actual infringements.") (citation omitted). Myco has never actively induced,

promoted, encouraged, or influenced use of AB Max for posterior blepharitis. (Ex. 1 at ¶ 6.)

As the letters "AB" in the product name suggest, Myco sells and promotes AB Max *only* for treating anterior blepharitis. (*See* Ex. 4.) Treating *anterior* blepharitis treats only "the *front* edge of the eyelid." (Ex. 3, p. 3, emphasis added.) In contrast, the '718 patent covers treatment of *posterior* blepharitis and is infringed only when treating the *inner* edge of the eyelid.

Blephex cannot argue that the "inner eyelid" limitations of the claims are mere surplusage. As detailed in § II.B., above, Blephex and Dr. Rynerson added those "inner eyelid" limitations to overcome PTO rejections and make the claims patentable. Blephex is estopped from asserting that the inner eyelid limitation can be ignored. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1367 (Fed. Cir. 2003) (when "a narrowing amendment has been made for a substantial reason relating to patentability . . . the presumption [is] that the patentee has surrendered all territory between the original claim limitation and the amended claim limitation.") (citations omitted).

Blephex may argue that some users of the AB Max product could possibly use the product to treat blepharitis in a way that infringes the claims. But "[t]he mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven." *DSU*, 471 F.3d at 1305 (citation and internal quotation marks omitted). Here, Blephex has no such evidence. Blephex cannot prove that Myco has actively induced infringement of the '718 patent.

## b. Blephex cannot prove that AB Max contributorily infringes under § 271(c)

"Contributory infringement liability arises when one 'sells within the United States . . . a component of a patented machine . . . knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use." 35 U.S.C. § 271(c) (2000)." *Golden Blount, Inc. v. Robert H. Peterson Co.*, 365 F.3d 1054, 1061 (Fed. Cir. 2004).

To prove contributory infringement under § 271(c), Blephex must show, *inter alia*, that AB Max has no substantial non-infringing use. *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1363 (Fed. Cir. 2012) ("Because [the patent owner] had the burden to prove the lack of substantial non-infringing uses, [the patent owner] was required to put forth evidence showing that the use of [the accused product] was not substantial."). Blephex cannot make that showing because AB Max has a substantial non-infringing use—the treatment of anterior blepharitis.

"A noninfringing use is 'substantial' when it is 'not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental."" *Toshiba Corp.*, 681 F.3d at 1362 (citation omitted). Use of AB Max to treat anterior blepharitis is none of those things. Blephex may argue that medical practitioners may choose to use AB Max to treat posterior blepharitis. But that is irrelevant to the issue of contributory infringement. "Where the product is equally capable of, and interchangeably capable of both infringing and substantial non-infringing uses, a claim for contributory infringement does not lie." *In re Bill of Lading Transm'n*, 681 F.3d 1323, 1338 (Fed. Cir. 2012).

Because treating anterior blepharitis is a substantial non-infringing use of AB Max, Blephex cannot prove contributory infringement.

#### 3. The medical practitioners (Myco's customers) who use AB Max are immune from liability under § 287(c)(1)

As explained above, AB Max is an FDA registered device for use by medical practitioners. Myco's only customers for AB Max are medical practitioners. (*See* Ex. 4, "For use by medical professionals only.") As Blephex knows, or should know, Myco's AB Max customers are immune from suit under 287(c)(1).<sup>4</sup>

The practitioners who own AlgerBrush II handles, *i.e.*, licensed ophthalmologists, ER physicians, and optometrists (Ex. 2), are medical

<sup>&</sup>lt;sup>4</sup> Section 287(c)(1) provides: "With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity."

practitioners as defined by § 287(c): "any natural person who is licensed by a State to provide the medical activity described in subsection (c)(1) or who is acting under the direction of such person in the performance of the medical activity." 35 U.S.C. § 287(c)(2)(B). A "medical activity" is "the performance of a medical or surgical procedure on a body." 35 U.S.C. § 287(c)(2)(A).<sup>5</sup> Indisputably, removing debris from an eyelid, whether anterior or posterior, using an AB Max attached to an AlgerBrush II is a medical procedure as defined by § 287(c)(2)(A).

Because Myco customers are medical practitioners immune from liability to Blephex, Blephex's threats of patent infringement made to Myco's customers are objectively baseless.

# B. Likelihood of success: Myco is likely to succeed on the merits of its unfair competition claims

Section 43(a)(1)(B) of the Lanham Act provides:

Any person who, on or in connection with any goods or services, . . . uses in commerce . . . any false or misleading description of fact, or false or misleading representation of fact, which—

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<sup>&</sup>lt;sup>5</sup> Medical activities do not include "(i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent." Use of AB Max does not fall within any of these exceptions. The '718 patent claims a process not a "machine, manufacture, or composition of matter," so exceptions (i) and (ii) do not apply. Likewise, the '718 patent is not a biotechnology patent, so exception (iii) does not apply.



(B) in commercial advertising or promotion misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,

shall be liable in a civil action by any such person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. §1125(a)(1)(B).

To establish a federal claim of unfair competition, Myco must prove: "(1) the defendant has made a false or misleading statement of fact concerning his product or another's; (2) the statement actually or tends to deceive a substantial portion of the intended audience; (3) the statement is material in that it will likely influence the deceived consumer's purchasing decisions; (4) the statement was introduced into interstate commerce; and (5) there is some causal link between the challenged statement and harm to the plaintiff." Eastman Outdoors, Inc. v. Blackhawk Arrow Co., 329 F.Supp.2d 955, 959 (E.D. Mich. 2004); see also Zenith Elecs. Corp. v. Exzec, Inc., 182 F.3d 1340, 1348 (Fed. Cir. 1999). Additionally, where a claim of unfair competition is based on marketplace representations of patent infringement, a plaintiff must also prove that the representations were made in bad faith and were "objectively baseless." Eastman Outdoors, 329 F.Supp.2d at 959; Zenith Elecs., 182 F.3d at 1353. Myco has established every element of a Section 43(a) claim and that Blephex (via Dr. Rynerson) acted in bad faith in asserting objectively baseless claims of patent infringement.

The first, second<sup>6</sup> and fourth elements of a Section 43(a) claim are met here because Dr. Rynerson deliberately misled optometrists attending SECO 2019 to believe that the AB Max infringes Blephex's patents, despite the fact that Myco did not and does not use the AB Max for treatment of any kind and Dr. Rynerson knew that Myco markets and sells the AB Max *solely* for the treatment of anterior blepharitis.

The third element—that the statement was likely to influence the deceived consumer's purchasing decisions—is also met, given that more than two-thirds of SECO 2019 attendees are expected to "make buying decisions or recommend purchases for their practice" and over one-half are expected to "make purchases onsite or within 1 year of attending SECO." (Ex. 7.) Dr. Rynerson had no reason to tell Myco's prospective customers that Myco was "totally infringing his patents" or that he'd be "taking action" (Ex. 8) other than to dissuade them from buying an AB Max tool.

For the fifth element, Dr. Rynerson's very public and false accusations caused Myco to suffer harm to its goodwill and reputation, as well as economic

<sup>&</sup>lt;sup>6</sup> Where, as here, a statement is literally false, or the plaintiff is seeking injunctive relief, or both, a plaintiff need only "present evidence of some sort demonstrating that consumers were misled." *See American Council, Certified Podiatric Phys. v. American Bd. Podiatric Surgery, Inc.*, 185 F.3d 606, 618 (6th Cir. 1999).

harm from the loss of prospective customers who may fear that purchasing the AB Max will involve them in a patent infringement lawsuit.

Finally, "if the patentee knows that the patent is . . . not infringed, yet represents to the marketplace that a competitor is infringing the patent, a clear case of bad faith representations is made out." *Zenith Elecs.*, 182 F.3d at 1354. And a claim of infringement is objectively baseless if the patent is "obviously invalid or plainly not infringed." *Globetrotter Software, Inc. v. Elan Comp. Grp., Inc.*, 362 F.3d 1367, 1375 (Fed. Cir. 2004). For the reasons stated in § IV.A. above, Dr. Rynerson statements were objectively baseless because the '718 patent was "plainly not infringed" by Myco's AB Max. The sale of a product cannot infringe a method claim, Myco only promotes the AB Max tool for the treatment of anterior blepharitis, and the users of the tool are immune from liability for infringement.

# C. Myco will suffer irreparable harm absent a preliminary injunction

"A plaintiff's harm from the denial of a preliminary injunction is irreparable if it is not fully compensable by monetary damages." *Certified Restoration*, 511 F.3d at 550. "[A] realistic prospect of lost sales and market share" causes harm to "goodwill and competitive position" that is irreparable because such losses are difficult to compute and compensate. *Collins Inkjet Corp. v. Eastman Kodak Co.*, 781 F.3d 264, 279 (6th Cir. 2015). Here, Myco will surely lose sales and suffer immeasurable harm to its reputation and goodwill if Blephex (via Dr. Rynerson or



other representatives) continues its public crusade to tarnish Myco's reputation and the AB Max with false claims of patent infringement and threats against potential customers. In contrast, Blephex suffers no harm if it is ordered to stop making false, baseless allegations of patent infringement.

#### D. The balance of harms favors a preliminary injunction

The Court must consider "whether the issuance of the injunction would cause substantial harm to others." *Certified Restoration*, 511 F.3d at 542. There would be no harm to Blephex if the Court issues the requested injunction because it would only preclude Blephex (and Dr. Rynerson) from continuing to make false accusations of patent infringement and baseless threats to sue non-party medical professionals. It would not prevent Blephex from competing fairly with Myco. *See Collins*, 781 F.3d at 280 (finding injunction would not harm defendant where it precluded anticompetitive conduct, but "[did] not prevent [defendant] from competing with [plaintiff] on a fair playing field"). Issuance of an injunction in this case would benefit consumers by preventing Blephex from stifling fair competition.

# E. Public interest weighs in favor of granting a preliminary injunction because the law promotes free and open competition

The patent system encourages "free competition in the exploitation of unpatented designs and innovations." Bonito Boats, Inc. v. Thunder Craft Boats,

*Inc.*, 489 US 141, 151 (1999). The Supreme Court has also remarked on "the law's reluctance to find liability when a defendant merely sells a commercial product suitable for some lawful use." *Metro-Goldwyn-Mayer Studios Inc. v. Grokster*, *Ltd.*, 545 US 913, 936 (2005). Treating anterior blepharitis is unpatented and Myco is free to sell AB Max to medical practitioners for the treatment of anterior blepharitis. *Id*.

The purpose of the Patent Act is to strike a balance that "encourage[s] innovation" and "avoid[s]... monopolies which stifle competition." *Bonito Boats*, 489 U.S. at 146. Therefore, enjoining conduct like Blephex and Dr. Rynerson's is a strong public interest. *See Lear v Adkins*, 395 US 653, 663 (1969) ("[T]he grant of monopoly power to a patent owner constitute[s] a limited exception to the general federal policy favoring free competition.")

#### V. CONCLUSION

For all reasons set forth above, Myco respectfully asks the Court to enjoin Blephex, its officers, agents, and those in active concert with it, from (1) making false allegations that Myco's AB Max infringes the '718 patent, and (2) making baseless threats to sue Myco's medical-practitioner potential customers of AB Max.

Respectfully submitted, **BROOKS KUSHMAN P.C.** 

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Dated: March 18, 2019

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#### **CERTIFICATE OF ELECTRONIC SERVICE**

I certify that on March 18, 2019, I electronically filed the foregoing <u>AMENDED</u> PLAINTIFF MYCO INDUSTRIES INC.'S MOTION FOR PRELIMINARY INJUNCTION AND BRIEF IN SUPPORT with the Clerk of the Court for the Eastern District of Michigan using the ECF System which will send notification to the following registered participants of the ECF System as listed on the Court's Notice of Electronic Filing: Dean W. Amburn and Lina A. Asmar.

A [Proposed] Order has also been submitted directly to the Judge for approval on the date stated above via the Court's ECF system and is also being sent via electronic mail to the parties listed above.

#### **BROOKS KUSHMAN P.C.**

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