

**United States Court of Appeals
for the Federal Circuit**

MYCO INDUSTRIES, INC.,
Plaintiff/Counter Defendant-Appellee

JOHN R. CHOATE,
Counter Defendant-Appellee

v.

BLEPHEX, LLC,
Defendant/Counter Plaintiff-Appellant

JAMES RYNERSON,
Defendant-Appellant

2019-2374

Appeal from the United States District Court for the Eastern District of Michigan in No. 2:19-cv-10645-GAD-EAS, United States District Judge Gershwin A. Drain.

Decided: April 3, 2020

PETER J. ARMENIO, Quinn Emanuel Urquhart & Sullivan, LLP, New York, NY, argued for defendant/counter plaintiff-appellant and defendant-appellant. Also represented by MATTHEW D. ROBSON, WILLIAM ADAMS.

CHRISTOPHER C. SMITH, Brooks Kushman PC,

Southfield, MI, argued for plaintiff/counter defendant-appellee and counter defendant-appellee. Also represented by THOMAS A. LEWRY, REBECCA JAMIE CANTOR.

Before NEWMAN, O'MALLEY, and TARANTO, *Circuit Judges*.
O'MALLEY, *Circuit Judge*.

We have jurisdiction over this case because it arises out of allegations of patent infringement. But, in its current posture, it is a case about free speech and a district court's authority to place prior restraints on that speech. Myco Industries, Inc. ("Myco") believed its competitor BlephEx, LLC ("BlephEx") engaged in unprotected speech—making false and misleading statements about Myco's product and whether it infringed BlephEx's patent covering such technology, U.S. Patent No. 9,039,718 (the "718 patent"). This appeal arises from the fact that, in response to Myco's request, the United States District Court for the Eastern District of Michigan preliminarily enjoined BlephEx's speech. The court granted Myco's motion for a preliminary injunction to enjoin BlephEx from making allegations of patent infringement and also from threatening litigation against Myco's potential customers. *Myco Indus., Inc. v. BlephEx, LLC*, Case No. 19-cv-10645, 2019 WL 4023789 (E.D. Mich. Aug. 27, 2019). BlephEx appeals the district court's order.

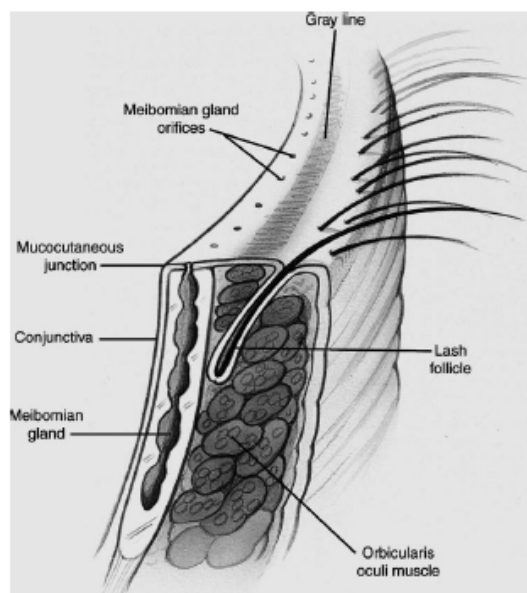
Because we find that the court abused its discretion by entering that preliminary injunction, we reverse, vacate, and remand.

I. BACKGROUND

Because the speech at issue relates to allegations of patent infringement and the good faith of any such allegations, we briefly describe the science involved and the '718 patent claims.

A. The Eyelid Margin and Ocular Disorders

The eyelid margin is a portion of the edge of the eyelid which encompasses the site of the eyelashes, the meibomian gland orifices, and the gray line. J.A. 718. The eyelid margin is divided into two regions, as demarcated by the gray line: (1) a posterior eyelid margin (“inner edge margin”)¹, including the meibomian gland orifices; and (2) an anterior eyelid margin (“outer edge margin”), including the eyelashes. J.A. 482–83.



J.A. 717.

¹ There is an ongoing claim construction dispute before the district court regarding the definition of “inner edge,” as recited by claim 1 of the ’718 patent. J.A. 1100, 1102. Myco concedes, however, that it “does not contest the definiteness of the phrases [in] this appeal” because the plain and ordinary meanings of these terms are “not relevant to the issues BlephEx raises in this appeal.” Appellee Br. 12 n.5.

There are several ocular diseases that affect the eyelid margin, such as blepharitis, meibomitis, and dry eye syndrome. '718 patent, Abstract. Blepharitis, which comes in two forms, is a condition characterized by inflammation of the eyelids and the formation of dandruff-like scales on the eyelashes. J.A. 2–3. Anterior blepharitis affects a portion of the outer edge margin while posterior blepharitis affects a portion of the inner edge margin. J.A. 3.

If a patient is diagnosed with eyelid margin disease, a doctor may prescribe a home treatment procedure, possibly in conjunction with antibiotics and/or topical steroids until the disease subsides. '718 patent, col. 1 ll. 27–32. Home treatment is typically a two-step process. *Id.*, col. 1, ll. 40–41. The patient first softens the eyelid margin debris by using a warm compress or a specialized liquid solution. *Id.*, col. 1 ll. 40–50. The patient then removes the debris by physically scrubbing the eyelid margin. *Id.* By cleaning debris from the base of the eyelashes and unclogging the pores of the meibomian glands, the patient improves the overall health of the eyelid margin, thereby reducing symptoms related to the disorder. *Id.*, col. 1 ll. 50–54. Unfortunately, this home treatment procedure is often met with limited success due to the practical difficulties of cleaning one's own eye with an imprecise instrument, such as a Q-tip or a fingertip. *Id.*, col. 1 ll. 56–59. While attempted self-treatment can temporarily abate a patient's symptoms, failure to completely treat the affected area allows for "subtle continuation of the disease." *Id.*, col. 2 ll. 3–5.

B. U.S. Patent No. 9,039,718

The '718 patent, entitled "Method and Device for Treating an Ocular Disorder," is generally directed to a method for treating ocular disorders by "using an electro-mechanical device to move a swab relative to the eye to create cylindrical movement that impacts debris present at the eyelid margin and effectively removes the debris from the eye to encourage healing and prevent further

digression of the health of the eye.” ’718 patent, Abstract. Put simply, the claimed method involves using an electro-mechanical device with a swab to remove debris from the affected eyelid margin area. *Id.* Figure 2A of the ’718 patent illustrates the swab of the claimed device treating the lower eyelid margin of a patient:

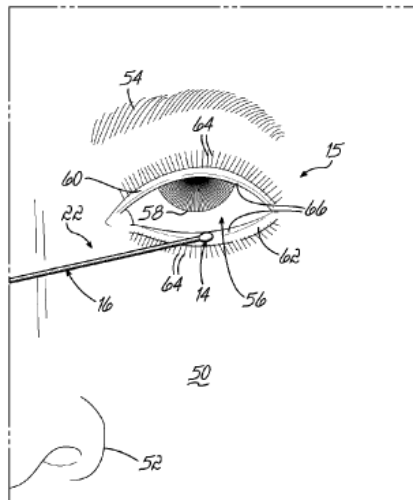


FIG. 2A

’718 patent, Figure 2A.

i. The ’718 Patent Claims

Independent claims 1 and 17, along with dependent claims 14 and 15, are relevant to this appeal and recite:

1. A method for treating an eye for an ocular disorder with a swab operably connected to an electro-mechanical 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 from 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 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 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.

'718 patent, col. 7 l. 30–col. 8 l. 57.

ii. Prosecution History

U.S. Patent Application No. 13/556,729, which issued as the '718 patent, was filed on July 24, 2012. As originally

filed, claim 1 recited a method for treating an eye for an ocular disorder with a swab connected to an electromechanical device, with the swab “*contacting a portion of the eye that includes the removable debris.*” J.A. 154 (emphasis added).

During prosecution, the examiner issued a non-final office action rejecting claim 1 as anticipated by U.S. Patent Application No. 2007/0060988 (“Grenon”). J.A. 296–299. According to the examiner, the reference disclosed a method for treating an ocular disorder with a swab connected to an electromechanical device. J.A. 297. During an examiner interview, however, the applicant distinguished its invention from Grenon, contending that, unlike Grenon, the claimed swab “contacts the inner surface of the eyelid or eyelid margin.” J.A. 321. The examiner “agreed that such a claim limitation would overcome Grenon [*sic*], since one would not use Grenon [*sic*] to contact the inner surface of the eyelid, as this would also result in the device in Grenon [*sic*] contacting the eyeball.” J.A. 321.

Following the examiner interview, the applicant submitted amendments to the original claims. One of those amendments added a limitation to claim 1: “the swab having at least a portion thereof configured to access an inner edge portion of the eyelid margin.” J.A. 324. The applicant explained that the added limitation overcame Grenon because “Grenon fails to disclose a swab having a portion configured to access an inner edge portion of the eyelid margin of the eye,” and “as agreed during the [examiner interview,] the apparatus of Grenon is not capable of contacting an inner edge portion of an eyelid margin.” J.A. 331. The applicant also added new claims, including then-claim 28 (which issued as claim 15) and then-claim 29 (which issued as claim 17). J.A. 326. Then-claim 28 recited “contacting the inner edge portion of the eyelid margin with the swab,” while then-claim 19 included “contacting at least an inner edge portion of the eyelid margin.” J.A. 326.

Following submission of the amendments, the examiner conducted another interview and “discussed a potential Examiner’s Amendment to incorporate the language regarding ‘contacting at least an inner edge portion of the eyelid margin’ of claim 29 into claim 1.” J.A. 338. The applicant’s patent attorney, however, responded that he would need to discuss this potential amendment with his client and thus, “no agreement was reached on the Examiner’s Amendment at this time.” J.A. 338. Ultimately, the potential Examiner’s Amendment was not incorporated into claim 1. Instead, to receive a notice of allowance, the applicant added another limitation to claim 1: “contacting a portion of the eye between the eye lashes and the inner edge of the eyelid margin.” J.A. 392. The ’718 patent issued on May 26, 2015.

C. Procedural History

i. The History of Myco and BlephEx

In August 2012, after filing U.S. Patent Application No. 13/556,729, the ’718 patent inventor, Dr. James Rynerson, contacted John Choate. J.A. 110. The men entered into a partnership. Choate agreed to help develop a commercial product based on the electromechanical device disclosed in the ’718 patent. J.A. 110–111. The final commercial product, a device used to clean the eyelid margin by practicing the methods claimed in the ’718 patent, was named the BlephEx (“the BlephEx product”) and was brought to market in 2013. J.A. 111, 723. In January 2014, Choate ended this relationship with Rynerson, apparently on less than cordial terms. J.A. 111. Sometime later, Choate became chairman of Myco Industries, Inc. J.A. 109.

In 2019, Myco began marketing the AB Max. J.A. 88, 109. The AB Max is an FDA registered device used by medical practitioners to treat anterior blepharitis. J.A. 109–110. The AB Max is an attachment for an Algerbrush II handle, which is “used by ophthalmologists, ER physicians and, [*sic*] optometrists who are trained and licensed to

remove foreign bodies from the eye of a patient.” J.A. 109–110.

In 2019, Rynerson and Choate both hosted booths at the Southern Educational Congress of Optometry (“SECO”) 2019 trade show in New Orleans. J.A. 112. During the trade show, Myco displayed its AB Max tool and handed out materials explaining the functionality and use of the tool to attendees. J.A. 112. None of the materials for the AB Max tool promoted or marketed the AB Max for treating posterior blepharitis, only anterior blepharitis. J.A. 112. Rynerson then approached the Myco booth and expressed concern about the AB Max device. J.A. 113.

Choate contends that, upon observing the AB Max device, Rynerson became hostile and accused the AB Max device of infringing the ’718 patent. J.A. 113. According to Choate, Rynerson made loud accusations of infringement within earshot of prospective customers, while videotaping at least part of the encounter on his cell phone. J.A. 113. A third party, Dr. Adam Farkas, emailed Choate after SECO 2019, informing Choate that he overheard Rynerson at the BlephEx booth repeating his claims to potential customers that the AB Max infringed his ’718 patent and that he would be “taking action.” J.A. 113, 522.

Rynerson’s version of the events is more subdued. Rynerson agrees that he saw Choate at the SECO 2019 show, but denies telling Choate that the AB Max infringed the ’718 patent. J.A. 575. Instead, Rynerson contends that he merely asked if Choate thought the AB Max product might infringe the ’718 patent. J.A. 575. Rynerson maintains that he did not threaten to sue anyone for patent infringement and was only looking to gain information about the AB Max because he thought that it looked very similar to the BlephEx product. J.A. 575. Rynerson states that he accepted a Doctor’s Brochure for the AB Max from Choate, took photos of Myco’s display booth, and promptly left. J.A. 575. Rynerson further maintains that he did not make any

video recordings, send Myco or Choate any form of correspondence alleging that the AB Max product infringes the '718 patent, or threaten any customer with patent infringement. J.A. 575–76.

ii. Myco's Declaratory Judgment Action

In March 2019, Myco filed a declaratory judgment action against BlephEx in the U.S. District Court for the Eastern District of Michigan. J.A. 29. Myco sought a declaratory judgment that it has not been and is not directly, indirectly, or contributorily infringing the '718 patent; a declaratory judgment that the claims of the '718 patent are invalid under 35 U.S.C. §§ 102, 103, and/or 112; and injunctive and monetary relief under Michigan and federal unfair competition law on the basis that Rynerson made patent infringement allegations regarding the AB Max at SECO 2019 in bad faith. J.A. 51–55.

Shortly after filing an amended complaint against BlephEx, Myco filed a motion for a preliminary injunction, seeking to bar BlephEx from (1) “Making false allegations that Myco's AB Max infringes the '718 patent” and; (2) “making baseless threats against Myco's medical-practitioner potential customers of AB Max.” J.A. 104. In its motion, Myco alleged that it had a strong likelihood of success on the merits of its patent non-infringement claims because, *inter alia*, (1) “[d]uring prosecution of the application for the '718 patent, Rynerson expressly limited the patent claims to a method of treating *posterior* blepharitis,” whereas Myco sells and promotes the AB Max “only for treating anterior blepharitis”; and (2) Myco's medical-practitioner customers are immune from liability under 35 U.S.C. § 287(c)(1). J.A. 92–99 (emphasis added). In response, BlephEx disputed Myco's assertion that the claims of the '718 patent are limited to treating posterior blepharitis, and argued that Myco's § 287(c)(1) medical immunity argument improperly relied on the assumption that all direct infringers of the AB Max are medical professionals.

J.A. 545–557. Briefing on the motion concluded in April 2019. J.A. 31.

A few months later, BlephEx moved the district court for leave to file supplemental briefing. J.A. 32–33. In its supplemental briefing, BlephEx noted that federal law requires a showing of bad faith in order to bar patentee speech and argued that its counterclaims of infringement demonstrate its objective good faith. J.A. 774–79. Myco opposed BlephEx’s motion, arguing that it failed to raise any new facts justifying additional briefing and consisted primarily of new arguments and case law that BlephEx should have asserted during the briefing period. J.A. 1006–1008. The district court denied BlephEx’s motion for leave to file a supplemental brief. J.A. 2, 34.

iii. The District Court’s
Preliminary Injunction Opinion

On August 27, 2019, the district court granted Myco’s amended motion for a preliminary injunction and enjoined BlephEx, its officers, agents, and those in active concert with BlephEx “from making allegations of patent infringement and from threatening litigation against [Myco’s] potential customers.” *Myco*, 2019 WL 4023789, at *9. In its opinion, the district court identified and discussed four preliminary injunction factors, as enumerated by the 6th Circuit: (1) likelihood of success on the merits; (2) irreparable injury without the injunction; (3) substantial harm to others; and (4) public interest. *Id.* at *3 (citing *Certified Restoration Dry Cleaning Network, L.L.C. v. Tenke Corp.*, 511 F.3d 535, 542 (6th Cir. 2007)).

Under the first factor, likelihood of success on the merits, the district court discussed each of Myco’s non-infringement and unfair competition claims. *Myco*, 2019 WL 4023789, at *3–7. The district court’s analysis of Myco’s non-infringement claim considered direct infringement, active inducement, and contributory infringement. *Id.* at *3–6. With respect to its direct infringement discussion, the

district court focused almost entirely on whether the claimed method recited in claim 1 is limited to treating posterior blepharitis. *Id.* at *3–5. According to the court, “the ’718 patent routinely describes the swab of the Bleph[E]x contacting the ‘inner edge portion of the eyelid margin’” and “effectively describe[s] the treatment of posterior blepharitis, because posterior blepharitis affects the inner edge of the eyelid.” *Id.* at *4. The district court also noted that “adding the ‘inner edge portion of the eyelid margin’ language was necessary in order for the PTO to issue a patent on the Bleph[E]x.” *Id.* Thus, the district court determined that the ’718 patent claims are limited to “treatment of posterior blepharitis.” *Id.* at *5. Because the district court found that “the ’718 patent[] is for use for the treatment of posterior blepharitis” and “the AB Max is for the treatment of anterior blepharitis,” the district court concluded “that Myco has demonstrated a strong likelihood of success on its claim that it does not directly infringe the ’718 patent.” *Id.* at *4–5.

The district court also determined that Myco had demonstrated a “strong likelihood of success” that Myco did not indirectly infringe any claims of the ’718 patent. As related to induced infringement, the district court held that “the record does not show that [Myco] or a third party directly infringed the ’718 patent,” or that “[Myco] induced any infringing acts.” *Id.* at *5. This conclusion was dependent on the district court’s determination that the ’718 patent claims are limited to treatment of posterior blepharitis. In concluding that Myco did not induce any infringing act, the district court relied on a video of Choate’s statements at the SECO conference, which demonstrated Choate marketing the AB Max as a treatment for anterior blepharitis. *Id.* The court therefore concluded “that there

is a strong likelihood of success on Plaintiff's contention that it did not induce infringement." *Id.*²

Finally, the district court maintained that any customers of the AB Max who are medical practitioners are not liable pursuant to § 287(c)(1) of the Patent Act. *Id.* at *6. And, because the court had already determined that "the AB Max does not directly or indirectly infringe the '718 patent," it concluded that "there is also a strong likelihood of success on [Myco]'s contention that Myco customers who are not medical practitioners are also not liable for infringement." *Id.*

After determining that (1) Myco had demonstrated a strong likelihood of success on its non-infringement patent claim³; (2) Myco had shown that it would suffer irreparable

² With respect to contributory infringement, the district court determined that, although Myco's AB Max device could be used "for the treatment of posterior blepharitis, which would infringe" on certain claims of the '718 patent, "practitioners could also solely use [it] for the treatment of anterior blepharitis, which does not infringe on the '718 patent." *Myco*, 2019 WL 4023789 at *6. "[B]ecause the AB Max has a substantial non-infringing use," the district court concluded that Myco demonstrated a strong likelihood of success that it is not liable for contributory infringement. *Id.* While the district court also discussed concepts of contributory infringement, because BlephEx does not push that theory of infringement on appeal, we decline to address it.

³ With respect to Myco's unfair competition claim, the district court found that "[t]he record does not establish that [Myco]'s version of the facts is more credible or accurate than [BlephEx]'s." *Myco*, 2019 WL 4023789, at *7. Accordingly, the district court held that it could not "establish that Defendant made any false or misleading statements about the AB Max" and concluded that Myco had

harm absent a preliminary injunction; (3) BlephEx had not shown that it would face substantial harm if a preliminary injunction issued; and (4) both parties' public interest considerations were equal, the district court concluded that upon balance, a preliminary injunction was appropriate. *Id.* at *8–9. The district court issued a preliminary injunction “enjoining [BlephEx], its officers, agents, and those in active concert with [BlephEx] from making allegations of patent infringement and threatening litigation against [Myco]’s potential customers.” *Id.* at *8.

BlephEx timely appealed the district court’s preliminary injunction order. We have jurisdiction over this appeal pursuant to 28 U.S.C. § 1292(a)(1).

II. DISCUSSION

We review a district court’s grant or denial of a preliminary injunction using the law of the regional circuit. *Macom Tech. Sols. Holdings, Inc. v. Infineon Techs. AG*, 881 F.3d 1323, 1328 (Fed. Cir. 2018). Under Sixth Circuit law, we review the district court’s ultimate determination as to whether the preliminary injunction factors weigh in favor of granting preliminary injunctive relief for an abuse of discretion. *Tumblebus Inc. v. Cranmer*, 399 F.3d 754, 760 (6th Cir. 2005). The question of whether a movant is likely to succeed on the merits is a question of law, which the Sixth Circuit reviews de novo. *Id.*

“not demonstrate[d] a strong likelihood of success on its unfair competition claims.” *Id.* The district court’s likelihood of success determination on Myco’s unfair competition claim is not at issue on appeal, though its factual finding regarding the nature of BlephEx’s statements is relevant to the questions we address.

A. The Requirement of “Bad Faith”

When considering a motion for a preliminary injunction, courts must balance:

- (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 the issuance of the injunction would cause substantial harm to others; and
- (4) Whether the public interest would be served by issuance of the injunction.

Id. But when a preliminary injunction prevents a patentee from communicating its patent rights, a court applies “federal patent law and precedent relating to the giving of notice of patent rights.” *GP Indus., Inc. v. Eran Indus., Inc.*, 500 F.3d 1369, 1373 (Fed. Cir. 2007). In such cases, the grant of a preliminary injunction is reviewed “in the context of whether, under applicable federal law, the notice of patent rights was properly given.” *Id.* We have further held that “federal law requires a showing of bad faith” before a patentee can be enjoined from communicating his patent rights. *Id.*

A showing of “bad faith” must be supported by a finding that the claims asserted were objectively baseless. *See id.* at 1374. An asserted claim is objectively baseless if no reasonable litigant could realistically expect success on the merits. *Id.* (citing *Profl Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993)).

i. The District Court Enjoined Patentee Speech Without a Finding of Bad Faith

The district court abused its discretion when it granted a preliminary injunction enjoining patentee speech without a finding of bad faith. Although a district court’s

discretion to enter a preliminary injunction is entitled to substantial deference, the patent laws permit a patentee to inform a potential infringer of the existence of its patent. *See, e.g.*, 35 U.S.C. § 287 (“Patentees . . . may give notice to the public that [a patented article] is patented”); *Va. Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 869 (Fed. Cir. 1997) (“[A] patentee must be allowed to make its rights known to a potential infringer so that the latter can determine whether to cease its allegedly infringing activities, negotiate a license if one is offered, or decide to run the risk of liability and/or the imposition of an injunction.”). Therefore, “communication to possible infringers concerning patent rights is not improper if the patent holder has a good faith belief in the accuracy of the communication.” *Mikohn Gaming Corp. v. Acres Gaming, Inc.*, 165 F.3d 891, 897 (Fed. Cir. 1998). In this case, the district court neither made a finding of bad faith nor even adverted to the requirement. To the extent the court made any factual findings relevant to bad faith, moreover, the court expressly declined to find that any of BlephEx’s statements were either false or misleading. *Myco*, 2019 WL 4023789, at *7. This alone warrants reversal.⁴ *See Coursey v. Comm’r of Soc. Sec.*, 843 F.3d 1095, 1097 (6th Cir. 2016) (“A district court abuses its discretion when it relies on clearly

⁴ Myco argues that BlephEx waived its argument that a showing of bad faith is a prerequisite to injunctive relief. Appellee Br. 26–28. We disagree. “While a party can waive his or her ability to appeal a ruling for failure to object, there can be no waiver here of the Judge’s duty to apply the correct legal standard.” *United States v. Ali*, 508 F.3d 136, 144 n.9 (3d Cir. 2007); *see also Brown v. Smith*, 551 F.3d 424, 428 n.2 (6th Cir. 2008) (“[T]he district court was ill-served in this regard by the petitioning party, who never argued that AEDPA deference did not apply until this appeal. Nevertheless, a party cannot ‘waive’ the proper standard of review by failing to argue it.”).

erroneous findings of fact, when it improperly applies the law, or uses an erroneous legal standard.”).

ii. Section 287(c) Does Not Mean That Allegations of Infringement Directed to Medical Practitioners Are Made in Bad Faith

Myco does not dispute that the district court failed to make an express finding of bad faith. Myco maintains, however, that the district court’s analysis was appropriate because the injunction “merely precludes BlephEx from alleging infringement and threatening litigation against Myco’s AB Max potential customers,” who are purportedly immune from infringement under 35 U.S.C. § 287(c). Appellee Br. 23. Myco argues that, under this narrower scope, “threatening [Myco’s potential customers] with infringement of the ’718 patent is objectively baseless and in bad faith.” Myco asks us to infer a finding of bad faith from the language of the injunction itself.

But the injunction is not limited to allegations of patent infringement against Myco’s potential customers. Rather, the district court’s injunction enjoins BlephEx from both: (1) making allegations of patent infringement in general; and (2) threatening litigation against Myco’s potential customers. *Myco*, 2019 WL 4023789, at *8–9. In addressing whether Myco demonstrated a strong likelihood of success with respect to its ’718 patent non-infringement claims, the court considered whether “[Myco] or a third party” directly or indirectly infringed the method claims. *Id.* at *5. If the district court’s injunction was as narrow as Myco now claims, the court would have restricted its analysis to a discussion of induced infringement based on the actions of Myco’s medical-practitioner customers. Indeed, the record reflects that Myco sought a broader injunction. For example, Myco’s motion for a preliminary injunction “asks the Court to enjoin Bleph[E]x, 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.” J.A. 104. The plain text of Myco’s request makes clear that Myco not only sought to preclude BlephEx from communicating with its medical-practitioner customers, but from making *any* “false allegations that Myco’s AB Max infringes the ’718 patent.” *Id.*⁵

Even assuming the district court’s injunction is narrowly tailored to allegations of infringement and threats of litigation against Myco’s potential customers, the “medical practitioner immunity” provision of § 287(c) does not blanketly preclude a patent owner from stating that a medical practitioner’s performance of a medical activity infringes a patent. Section 287(c) recites:

With respect to a medical practitioner’s performance of a medical activity that constitutes an infringement under section 271(a) or (b), the provisions of sections 281, 283, 284, and 285 shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.

35 U.S.C. § 287(c)(1).

The plain text of the statute does not state that a medical practitioner is “immune from infringement,” as the district court found and Myco urges. Rather, the text establishes that, if a medical practitioner’s performance of a medical activity infringes a patent claim, the patentee cannot seek a remedy for such infringement against the practitioner or related health care entity. *See* 35 U.S.C.

⁵ As noted above, while Myco only sought to enjoin false allegations regarding patent infringement, the district court expressly found that the record did not permit a conclusion that any of BlephEx’s claims were either false or misleading.

§§ 281 (remedies), 283 (injunctions), 284 (damages), 285 (attorneys' fees). The act provides immunity to certain infringers, but it does not render them non-infringers. As we have explained, moreover, a medical practitioner's direct infringement of a method claim may form the basis for a claim of indirect infringement against a medical device manufacturer. *Barry v. Medtronic, Inc.*, 914 F.3d 1310, 1334 (Fed. Cir. 2019) (finding that "[s]ubstantial evidence supports the jury's finding of underlying direct infringement by surgeons," as relevant to the jury's finding that Medtronic induced others to infringe). Accordingly, Myco cannot simply hide under the umbrella of § 287(c) and argue that any alleged statements regarding medical practitioner infringement were made in bad faith. Rather, Myco must establish that BlephEx's patent infringement statements, whether made generally or to medical practitioners, were objectively baseless.

With respect to threats of *litigation* against Myco's potential customers, there is no evidence that BlephEx or Rynerson ever made such a threat. The parties submitted conflicting testimony regarding Rynerson's actions at the SECO 2019 trade show, but even Choate's memory of the events fails to recall Rynerson threatening Myco's potential customers with either patent infringement or litigation relating thereto. J.A. 113 ("Dr. Rynerson approached the Myco booth and became hostile and combative stating that the AB Max infringes Dr. Rynerson's patent."). And when Dr. Farkas, a fellow SECO 2019 attendee, sent an email to describe his observations of Rynerson's statements, he could only report that "[Rynerson] said that the AB Max technology was 'totally infringing on his patents' and that he'd be 'taking action.'" J.A. 522.

Myco insists that Dr. Farkas's email demonstrates that BlephEx threatened potential customers with litigation because a customer, overhearing Rynerson's intent to "take action," would infer a threat of litigation. *See* Oral Arg. at 28:50 ("A doctor hearing a statement that 'I'm going to take

action on this patent' that covers exactly what [she does] in [her] office—I think . . . that would be a threat on a doctor, or could be taken as a threat on a doctor, certainly.”), <http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2019-2374.mp3>. But Myco's argument asks the court to assume, without any supporting evidence, that a doctor would have interpreted Rynerson's general statements about the AB Max as both an accusation of patent infringement and a threat of litigation against the doctor herself.

Because the record lacks any evidence that BlephEx or Rynerson “threaten[ed] [Myco's potential customers] with infringement of the '718 patent” or, more specifically, with litigation relating thereto, Myco's implied “bad faith” argument fails. Appellee Br. 23. Where there was no finding of bad faith, let alone an acknowledgment of that requirement, the district court's decision to enjoin BlephEx's patent speech was an abuse of discretion.

Myco finally argues that, regardless of whether the district court made a finding of bad faith—either express or implied—the district court properly enjoined BlephEx from making general allegations of infringement because “[the Federal Circuit] has affirmed the grant of an injunction to plaintiffs in patent-based declaratory judgment cases.” Appellee Resp. Br. 29. In support of its argument, Myco cites to *Unitronics (1989) (R”G) Ltd. v. Gharb*, 318 Fed. App'x 902 (Fed. Cir. 2008), where the district court granted Unitronics' summary judgment motion of non-infringement and, as part of the final judgment, enjoined Gharb from “threatening Unitronics and its customers with infringement litigation.” 318 Fed. Appx. at 903–04. In a non-precedential decision, we affirmed the district court's final judgment of non-infringement, addressing the merits of the infringement issue—not the propriety of its injunction. *Id.* at 905. *Unitronics* does not address the injunction issue at all and does not establish precedent, contrary to *GP Industries*, that a district court may enjoin patentee speech without a finding of bad faith. *See, e.g., Elbit Sys. Land & CAI*

Ltd. v. Hughes Network Syst., LLC, 927 F.3d 1292, 1305 (Fed. Cir. 2019); *Arthrex, Inc. v. Smith & Nephew, Inc.*, 880 F.3d 1345, 1349 (Fed. Cir. 2018); *Special Devices, Inc. v. OEA, Inc.*, 269 F.3d 1340, 1346 (Fed. Cir. 2001).

iii. The District Court’s Conclusion that Myco Has a
“Strong Likelihood of Success on the Merits”
of its Non-Infringement Claim Must Be Vacated

To the extent the court enjoined general allegations of infringement—no matter where directed—that injunction is predicated on the court’s conclusion that use of Myco’s product likely does not directly infringe the claims of the ’718 patent. That conclusion, like all conclusions regarding infringement, could only be reached after a two-step process: a construction of the claims of the patent and a conclusion that use of BlephEx’s product does not likely read on those claims.⁶ *Myco*, 2019 WL 4023789, at *4–5. But the key predicate for the court’s finding that use of the AB Max likely does not directly infringe the ’718 patent is the conclusion that the AB Max is promoted for the treatment of *anterior* blepharitis, while the claims of ’718 patent are directed to posterior blepharitis. *Id.* at *5. There are several problems with that predicate.

The court’s claim construction that limits the scope of the claims to the treatment of posterior blepharitis is faulty

⁶ Although Myco argues in its brief that the district court “did not construe any claim terms to decide the preliminary injunction motion,” Appellee Br. 30, it conceded during oral argument that the district court necessarily conducted claim construction in order to determine whether Myco directly or indirectly infringed the ’718 patent claims. *See* Oral Arg. at 25:38 (“I don’t disagree that for purposes of finding whether the court erred in finding non-infringement, the court will have to look at the meaning of the term, the context of the limitation, specifically.”).

in a number of ways, ignoring key governing principles of law. In concluding that use of the AB Max likely does not infringe the '718 patent, the district court determined that the '718 patent claims are limited to “the treatment of posterior blepharitis” because “the '718 patent routinely describes the swab of the Bleph[E]x contacting the ‘inner edge portion of the eyelid margin.’” *Id.* at *4–5. But the plain language of the '718 patent claims does not state that the swab must contact the inner edge or that the claimed method is limited to treatment of posterior blepharitis. For example, claim 1 recites a swab “having at least a portion thereof configured to access an inner edge portion of the eyelid margin,” but does not state that any contact by the swab must be limited to the inner edge portion of the eyelid margin. '718 patent, col. 7 ll. 34–37. And unlike claims 14, 15, and 17, claim 1 does not require contacting or accessing “at least an inner edge portion of the eyelid margin.” *Compare* '718 patent, col. 7 ll. 34–37, *with* '718 patent, col. 8 l. 40, *and* '718 patent, col. 8 l. 43, *and* '718 patent, col. 8 ll. 54–55. Accordingly, reading such a limitation into claim 1 would appear to violate the doctrine of claim differentiation and render dependent claims 14, 15, and 17 superfluous. *See Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1348 (Fed. Cir. 2012) (“[T]he presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.”).⁷

⁷ We also remind the district court that limitations from different dependent claims should not be interpreted as if they were general statements of disavowal from the written description. *Compare Myco*, 2019 WL 4023789, at *2 (combining separate limitations from claims 1, 14, 15, and 17 as evidence that “the patent consistently states that the Bleph[E]x is for use with the ‘inner edge portion of the eyelid margin.’”).

During prosecution of the patent application, the applicant rejected the examiner's suggestion to add "contacting at least an inner edge portion of the eyelid margin" to claim 1. J.A. 331, 338, 392. Instead, the applicant and examiner compromised with the limitation, "contacting a portion of the eye between the eye lashes and the inner edge of the eyelid margin," implying that claim 1 recites a method of using a device with the *capability* of accessing the inner edge, but not *requiring* such contact during use. J.A. 392. Based on this back-and-forth, the court concluded that the "inner edge portion of the eyelid" language was important to allowance of the patent claims, and determined that the applicant's statements and amendments had narrowed the scope of the claims. J.A. 3, 12. But the court did not decide whether the patentee had clearly and unmistakably disavowed the claim scope, as would be required to depart from the meaning of the term provided in the claims and the written description. *See Sorensen v. Int'l Trade Comm'n*, 427 F.3d 1375, 1378–79 (Fed. Cir. 2005) ("Disclaimers based on disavowing actions or statements during prosecution . . . must be both clear and unmistakable."). Such a finding would be necessary before prosecution history may constitute a disclaimer of claim scope.⁸

⁸ That is not to say that prosecution actions or statements must be "clear and unmistakable" in order to inform a court's claim construction. If a claim term is ambiguous based on the plain language of the claims and the written description, we may look to the prosecution history for guidance. For example, in *Personalized Media Comm'cns, LLC v. Apple, Inc.*, Case No. 18-1936 (Fed. Cir. Mar. 13, 2020), we held that an applicant's "repeated and consistent statements during prosecution, along with its amendment to the same effect, are decisive as to the meaning of the disputed claim term—even if those statements do not rise to the level of a disclaimer." Slip op. at 18. Our precedent

The district court's non-infringement analysis also frequently conflates the invention claimed in the '718 patent with the BlephEx product. *See, e.g., Myco*, 2019 WL 4023789, at *4 (“However, the '718 patent routinely describes the swab of the Bleph[Ex] contacting the ‘inner edge portion of the eyelid margin.’”); *id.* (“Further, adding the ‘inner edge portion of the eyelid margin’ language was necessary in order for the PTO to issue a patent on the Bleph[Ex].”); *id.* at *5 (“Defendant’s Bleph[Ex] tool, according to the '718 patent, is for use for the treatment of posterior blepharitis.”). The law is clear, however, that “infringement is determined on the basis of the claims, not on the basis of a comparison with the patentee’s commercial embodiment of the claimed invention.” *Int’l Visual Corp. v. Crown Metal Mfg. Co.*, 991 F.2d 768, 772 (quoting *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1578 (Fed. Cir. 1984)). Similarly, claim construction, from which an infringement analysis depends, focuses on the recited limitations of the *claims*, not on the features of a commercial embodiment of the invention.

While we “will not lightly intrude upon a district court’s discretionary decision to issue only a tentative claim construction and to base its resolution of a preliminary injunction motion upon that tentative claim construction,” *Jack Guttman, Inc. v. Kopykake Enters., Inc.*, 302 F.3d 1352, 1361 (Fed. Cir. 2002), our conclusion that there are errors in the claim construction analysis employed requires that we vacate that claim construction and remand for further

addressing the general role of intrinsic evidence in claim construction, however, can be distinguished from the doctrine of prosecution disclaimer, wherein a patentee may narrow the scope of a claim term after he has clearly and unmistakably disavowed a certain meaning to receive a notice of allowance. *Tech. Props. Ltd. LLC v. Huawei Techs. Co.*, 849 F.3d 1349, 1357-58 (Fed. Cir. 2017).

consideration of what precisely is claimed in the claims of the '718 patent. Vacating the court's claim construction necessitates that we also vacate the court's finding regarding Myco's likelihood of success on its non-infringement contentions. In turn, that requires that we vacate the court's preliminary injunction with respect to BlephEx's ability to make generalized allegations of infringement with respect to the '718 patent.

III. CONCLUSION

Speech is not to be enjoined lightly. Here, there is not even a finding, let alone a finding supported by evidence and a correct view of the law, that the speech restrained was either false or misleading. The district court abused its discretion when it granted a preliminary injunction enjoining BlephEx from making allegations of patent infringement without a finding of bad faith and with no adequate basis to conclude that allegations of patent infringement would be false or misleading. It also abused its discretion in enjoining BlephEx from threatening Myco's potential customers with litigation where there was not only no finding of bad faith but no evidence in the record that any such threats had even been made. We therefore reverse and vacate the district court's preliminary injunction, and remand.

REVERSED, VACATED, AND REMANDED

COSTS

No costs.