United States Court of Appeals for the Federal Circuit

BLEPHEX, LLC,
Plaintiff-Appellee

v.

MYCO INDUSTRIES, INC., JOHN R. CHOATE,
Defendants-Appellants

2021-1149, 2021-1365

Appeals from the United States District Court for the Eastern District of Michigan in No. 2:19-cv-13089-GAD-EAS, Judge Gershwin A. Drain.

Decided: February 3, 2022

PETER J. ARMENIO, Quinn Emanuel Urquhart & Sullivan, LLP, New York, NY, argued for plaintiff-appellee. Also represented by WILLIAM ADAMS, MATTHEW D. ROBSON; ALEXANDER HALE LOOMIS, Boston, MA.

THOMAS A. LEWRY, Brooks Kushman PC, Southfield, MI, argued for defendants-appellants. Also represented by REBECCA JAMIE CANTOR, CHRISTOPHER C. SMITH.

Before MOORE, *Chief Judge*, SCHALL and O'MALLEY, *Circuit Judges*.

O'MALLEY, *Circuit Judge*.

In February 2019, Myco Industries, Inc. ("Myco") began marketing a product it called the AB Max at a trade show in New Orleans. The AB Max is a device for treating blepharitis.[1] A month later, BlephEx, LLC ("BlephEx") filed an application that would become United States Patent Number 10,449,087 ("the '087 patent"). On October 22, 2019, the United States Patent and Trademark Office issued the '087 patent, entitled "Instrument for Treating an Ocular Disorder." The same day, BlephEx sued Myco and its chairman, John R. Choate, in the Eastern District of Michigan, alleging that the AB Max infringed claim 16 of the '087 patent.[2] Soon thereafter, the district court granted a preliminary injunction enjoining Myco and those acting on its behalf from, *inter alia*, selling, distributing, or offering to sell or distribute the AB Max product. *See BlephEx, LLC v. Myco Indus., Inc.*, No. 2:19-CV-13089, 2020 WL 5951504 (E.D. Mich. Oct. 8, 2020) ("*Preliminary Injunction Decision*"); *BlephEx, LLC v. Myco Indus., Inc.*, No. 2:19-CV-13089, 2020 WL 7134932 (E.D. Mich. Nov. 25, 2020) ("*Reconsideration Decision*"). Myco appealed.

Because the district court did not abuse its discretion in granting the preliminary injunction, clearly err in its underlying factual findings, or abuse its discretion in setting the scope of the preliminary injunction, we affirm.

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[1] Blepharitis is a chronic inflammatory disease of the eyelids and eyelid margins that causes a buildup of scurf or debris. *See* U.S. Patent No. 10,449,087 col. 1 ll. 24–25.

[2] There is a history of enmity among the parties. While the parties spill a fair amount of ink on that history, we do not. It did not factor into the district court's judgment and is, thus, irrelevant to our conclusions.

I. BACKGROUND

A. The '087 Patent

The '087 patent discloses "[a]n instrument for removing debris from an eye during the treatment of an ocular disorder." '087 Patent Abstract. The claimed device may be used to treat blepharitis.

According to the '087 patent, treatment of blepharitis historically involved home treatment in which the patient would physically scrub the eyelid margin with a cotton swab, fingertip, or scrubbing pad to remove debris, oil, and scurf. '087 Patent col. 1 ll. 30–61. The '087 patent claims that "patients routinely fail to totally cleanse" the eyelid margin with this home treatment method. '087 Patent col. 2 ll. 12–14. To remedy this problem, the '087 patent discloses a swab attached to an electromechanical device for eye care professionals to use to clean patients' eyelid margins and eyelashes.

The '087 patent has 20 method claims. BlephEx asserted claim 16, and it was on that claim that BlephEx predicated its request for a preliminary injunction. Claim 16 recites:

> 16. 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 a portion of the eyelid margin; and
> >
> > while the swab is being moved by the electromechanical device, contacting a 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.

B. The Preliminary Injunction

As noted, BlephEx sought a preliminary injunction. The district court found that all relevant factors weighed heavily in favor of a preliminary injunction and, thus, granted BlephEx's motion. The district court concluded that (1) BlephEx had a strong likelihood of success on the merits; (2) BlephEx would suffer irreparable harm in the absence of preliminary relief; (3) preliminary relief would not unduly harm others; and (4) an injunction would serve the public interest.

The likelihood of success on the merits factor is at issue in this appeal. The district court's finding that BlephEx established a strong likelihood of success had multiple prongs, moreover, and Myco challenges only one. Specifically, the district court first found that BlephEx established that it was likely to prove direct infringement by Myco. Myco does not appeal this finding. The district court also found that BlephEx was likely to prove that Myco and Mr. Choate induced and contributed to infringement of claim 16. Myco, again, does not appeal these findings. The conclusion Myco challenges is that Myco failed to demonstrate a substantial question of validity. The district court was unconvinced by Myco's argument that the '087 patent is likely invalid over U.S. Pat. Pub. No. 2013/0331768 ("Nichamin").

Nichamin is a published patent application entitled "Eye Treatment." It describes a "novel combination of microdermabrasive along with a therapeutically effective amount of an isoprenoidal essential oil" useful for treatment or prevention of ocular disorders, diseases, or syndromes, such as blepharitis. J.A. 1446 (¶ 48). It also discloses "kits and methods for treating and preventing" various eye conditions and for cleaning healthy eyes. J.A. 1446 (¶ 50). Nichamin's Figure 2 shows a wand being used to remove debris from an eyelid margin:

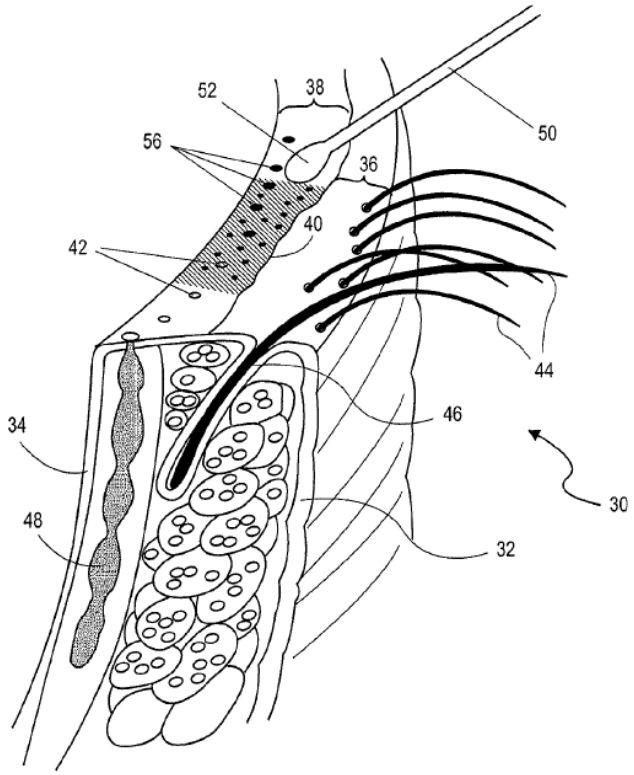

FIG. 2

J.A. 1446–47 (¶ 54); J.A. 1438. And Nichamin's Figure 3 depicts an electromechanical device used to apply the novel composition:

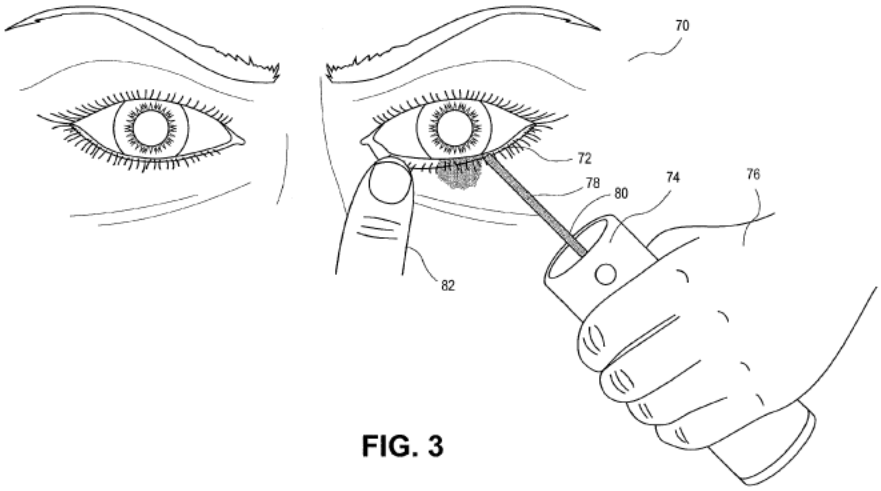

FIG. 3

J.A. 1448 (¶ 65); J.A. 1439.

Myco argued before the district court that these two figures show different perspectives of the same embodiment—an electromechanical device (depicted in Figure 3) equipped with a swab (depicted in Figure 2) used to contact the eyelid margin. The district court disagreed. It found that Nichamin's Figures 2 and 3 depict two *different* embodiments and that nothing in Nichamin suggested combining the two.

The district court thus found that Myco had not presented a substantial question of anticipation based on Nichamin. The court noted that a prior art reference must disclose all elements of a claim "arranged as in the claim" to anticipate. *Preliminary Injunction Decision*, 2020 WL 5951504, at *6 (quoting *Finistar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1334–35 (Fed. Cir. 2008)). Because Nichamin does not disclose combining the applicator device

of the embodiment depicted in Figure 3 with a swab, the district court found that Nichamin fails to disclose the limitation of a "swab [] being moved by the electromechanical device," and, thus, cannot anticipate claim 16. *Id.*

The district court also noted that Nichamin was considered during examination of the '087 patent application. It rejected Myco's argument that the examiner did not consider Nichamin because he did not substantively discuss it. *See Preliminary Injunction Decision*, 2020 WL 5951504, at *6 (citing *Tinnus Enters., LLC v. Telebrands Corp.*, 733 F. App'x 1011, 1020 (Fed. Cir. 2018)) (noting that it is "presumed that public officials do their assigned jobs").

The district court then found that Myco's "obviousness argument is unsupported with any expert evidence demonstrating that it would have been obvious to one of ordinary skill in the art to attach a swab to the end of Nichamin's hand-held device." *Id.* It found that Myco also failed "to explain how one of ordinary skill in the art would have addressed the safety concerns of attaching a swab that is soaked in an abrasive to the Nichamin hand-held device." *Id.* Without more, the district court concluded, it could not find that Myco had raised a substantial question of obviousness.

Because it concluded that BlephEx established a strong likelihood of proving its infringement claim, and that Myco failed to present a substantial question of validity, the district court concluded that the likelihood of success factor favored entry of a preliminary injunction. After finding that the remaining three factors similarly militated in favor of granting a preliminary injunction, the district court granted BlephEx's motion. It later denied Myco's motion to reconsider.

The district court adopted BlephEx's proposed preliminary injunction language and enjoined Myco from "using, offering for sale, and/or selling in the United States any ABMax™ device, including any disposable swab designed

to be used with any ABMax™ device." *Reconsideration Decisio*n, 2020 WL 7134932, at *4.

The district court rejected Myco's argument that the preliminary injunction was overbroad because the AB Max has non-infringing uses. The district court found this argument both untimely and without merit. It found Myco's arguments and evidence presenting only hypothetical non-infringing uses were outweighed by evidence that the only actual use of the AB Max was to treat anterior blepharitis—a use that the district court found would likely infringe claim 16. The district court thus concluded that its injunction was not overbroad.

Myco appealed. We have jurisdiction under 28 U.S.C. § 1292(c)(1).

II. DISCUSSION

Myco makes three arguments on appeal. First, it argues that it presented a substantial question as to the validity of claim 16 of the '087 patent on both anticipation and obviousness grounds. Second, it argues that the preliminary injunction improperly upset the status quo. Third, it argues that the preliminary injunction is overbroad. We address each argument in turn.

A. Substantial Question of Validity

Myco argues that we should vacate the injunction because claim 16 of the '087 patent is vulnerable to an invalidity challenge based on Nichamin. Myco first argues that it presented a substantial question of anticipation based on Nichamin Figures 2 and 3, which it asserts depict only one embodiment. It then argues that, even if Figures 2 and 3 depict different embodiments, a skilled artisan would combine those embodiments to anticipate claim 16 because the "applicator" depicted in Figure 3 can be a swab. Myco further argues that the district court improperly deferred to the patent examiner's allowance of the '087 patent over Nichamin. Finally, Myco argues that, even if it has not shown

a substantial question of anticipation, "it is a small step to obviousness"—that "it would have been common sense, and therefore obvious, to use a swab with Nichamin's Figure 3 device." Appellant's Br. 40–41. We do not find Myco's arguments persuasive. We address Myco's anticipation and obviousness arguments below. But, first, we address the burdens of proof in the preliminary injunction inquiry and the standard of review we apply to the district court's finding that Myco failed to raise a substantial question of validity.

1. Burdens of Proof

A party may obtain a preliminary injunction by showing that (1) it is "likely to succeed on the merits," (2) it is "likely to suffer irreparable harm in the absence of preliminary relief," (3) the "balance of equities tips in [its] favor," and (4) "an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The burden is always on the movant to show that it is likely to succeed on the merits. And in the context of a patent infringement suit, "[a] patent holder seeking a preliminary injunction bears the burden of establishing a likelihood of success on the merits with respect to the patent's validity." *Entegris, Inc. v. Pall Corp.*, 490 F.3d 1340, 1351 (Fed. Cir. 2007) (citing *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1351 (Fed. Cir. 2000)). Absent an invalidity defense, "the very existence of the patent with its concomitant presumption of validity satisfies the patentee's burden of showing a likelihood of success on the validity issue." *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1377 (Fed. Cir. 2009) (citations omitted). But if the accused infringer presents a substantial question of validity, "i.e., asserts an invalidity defense that the patentee cannot prove 'lacks substantial merit,' the preliminary injunction should not issue." *Entegris*, 490 F.3d at 1351 (quoting *Genentech, Inc. v. Novo Nordisk*, 108 F.3d 1361, 1364 (Fed. Cir. 1997)).

To show invalidity at trial, Myco will have "the ultimate burden of persuasion to prove invalidity by clear and convincing evidence, as well as the initial burden of going forward with evidence to support its invalidity allegation." *Titan Tire*, 566 F.3d at 1376 (citing *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008)). At the preliminary injunction stage, however, those burdens are "tailored to fit the preliminary injunction context." *Id.* at 1377. If an alleged infringer attacks the validity of a patent at the preliminary injunction stage, as Myco has, it bears the initial burden "to come forward with evidence of invalidity," just as it would at trial. *Id.* If the alleged infringer comes forward with such evidence, the district court should then consider "the evidence on both sides of the validity issue" to determine if the alleged infringer has raised a substantial question of validity. *Id.* at 1379 (citations omitted).

Myco need not, to defeat a preliminary injunction, prove invalidity by clear and convincing evidence, as it must to succeed at trial. *Id.* (citing *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1358 (Fed. Cir. 2001)). It need only present evidence showing that there is a substantial question of validity despite the presumption of patent validity and BlephEx's arguments in favor of validity, such that BlephEx's likelihood of success is in question. *Titan Tire*, 566 F.3d at 1377–79. Again, the ultimate burden is on BlephEx to show that it is likely to succeed on the merits to obtain the extraordinary remedy of a preliminary injunction, including "on the validity issue." *Titan*, 566 F.3d at 1377. But the initial burden is on Myco to produce some evidence to raise a substantial question of validity. *Id.* at 1377. To fulfill that burden, Myco need only "assert[] a defense that [BlephEx] cannot show 'lacks substantial merit.'" *See Genentech*, 108 F.3d at 1364.

2. Standard of Review

We review a district court's grant of a preliminary injunction under the law of the regional circuit, in this case, the Sixth Circuit. *See Macom Tech. Sols. Holdings, Inc. v. Infineon Techs. AG*, 881 F.3d 1323, 1328 (Fed. Cir. 2018). The Sixth Circuit reviews a district court's decision to issue a preliminary injunction under the "highly deferential" abuse of discretion standard. *DV Diamond Club of Flint, LLC v. Small Bus. Admin.*, 960 F.3d 743, 746 (6th Cir. 2020) (quoting *Certified Restoration Dry Cleaning Network, L.L.C. v. Tenke Corp.*, 511 F.3d 535, 541 (6th Cir. 2007)). The Sixth Circuit will reverse a district court's grant of a preliminary injunction "only if the district court 'relied upon clearly erroneous findings of fact, improperly applied the governing law, or used an erroneous legal standard.'" *Id.* (quoting *S. Glazer's Distrib. of Ohio, LLC v. Great Lakes Brewing Co.*, 860 F.3d 844, 849 (6th Cir. 2017)).

Myco incorrectly asserts that we should review whether it presented a substantial question of patent validity *de novo*. That is not the case. Although we review a district court's grant of a preliminary injunction under the law of the regional circuit, "we give dominant effect to Federal Circuit precedent insofar as it reflects considerations specific to patent issues." *See Macom Tech.*, 881 F.3d at 1328 (quoting *Mikohn Gaming Corp. v. Acres Gaming, Inc.*, 165 F.3d 891, 894 (Fed. Cir. 1998)). Whether a patentee has shown a likelihood of success on the merits is one such area where we apply our own law, as it is a question specific to patent law. *See Revision Mil., Inc. v. Balboa Mfg. Co.*, 700 F.3d 524, 526 (Fed. Cir. 2012). In the context of a preliminary injunction, we review the question of whether a movant has shown a likelihood of success in showing patent validity for abuse of discretion. *Titan Tire*, 566 F.3d at 1384 ("[W]e cannot say the trial court abused its discretion in concluding that Titan was unlikely to withstand Case's challenge to the validity of the '862 patent on

obviousness grounds."). We review the underlying issue of whether the patent challenger's asserted prior art raises a substantial question of validity, a factual issue, for clear error. *Amazon.com*, 239 F.3d at 1358 ("We review the district court's assessment of prior art references for clear error.").

3. Anticipation

Myco's primary anticipation argument is premised on its assertion that Nichamin's Figures 2 and 3 depict the same embodiment—an electromechanical device with a swab. We conclude that the district court did not clearly err when it concluded that Figures 2 and 3 depict separate embodiments.

Figure 2 shows a wand contacting a portion of the eyelid margin. J.A. 1446 (¶ 54). Figure 3 shows a hand-held device with an applicator—which Myco admits is not a swab[3]—used to chafe the eyelid margin. J.A. 1448 (¶ 65). Because neither figure shows "a swab operably connected to an electromechanical device" where the swab contacts a portion of the eyelid margin as required by claim 16, Myco's argument that Figures 2 and 3 depict the same anticipating embodiment fails to raise a substantial question of validity. "[I]t is not enough that the prior art reference . . . includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention" to show anticipation. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008) (citing *In re Arkley*, 455 F.2d 586, 587 (C.C.P.A. 1972)).

For the first time in its reply brief, Myco argues that, under our precedent in *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331 (Fed. Cir. 2016), a prior art reference that

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[3] *See* Oral Arg. at 5:45–6:00, available at https://oralarguments.cafc.uscourts.gov/dfault.aspx?fl=21-1149_06092021.mp3.

lacks "an express discussion of the actual combination" "may still anticipate if that reference teaches that the disclosed components or functionalities may be combined and one of skill in the art would be able to implement the combination." *Id.* at 1344 (citing *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1383 (Fed. Cir. 2015)). As this argument was not presented to the district court, Myco has failed to preserve it. Even if we were to consider it, moreover, we would be unpersuaded.

Myco argues that the level of skill in the relevant art is extremely high, agreeing with BlephEx that "an ordinary artisan 'would have highly advanced skill—at least a doctorate degree (a Doctor of Medicine (MD) or Doctor of Optometry (DO) degree) with at least two to five years of experience treating eyelid margin disease including blepharitis." Appellant's Reply Br. 13–14. Myco argues that the "highly skilled ordinary artisan here would 'at once envisage' the claimed combination from Nichamin's teachings." Appellant's Reply Br. 11 (quoting *Chamberlain Grp., Inc. v. Techtronic Indus. Co.*, 935 F.3d 1341, 1350 (Fed. Cir. 2019)). But Myco offers nothing other than attorney argument as to what the highly skilled artisan would do. Although Myco need not present the kind of evidence that would be required at trial, a substantial question of validity cannot be manufactured through mere supposition about what an artisan with highly advanced skill in the medical field might do.

Myco next argues that the "applicator" of Nichamin's Figure 3 can be a swab. Appellant's Br. 33. None of Myco's arguments are convincing. Myco first points us to Figure 3 for this contention. But, as explained above, the district court did not clearly err in finding that Figure 3 merely depicts a hand-held device dispensing a mixture from an applicator; it does not depict a swab. J.A. 1448 (¶ 65).

Myco next points to Nichamin's paragraph 66, which explains that a composition "may be dispensed in any way

(e.g., from an applicator/device/wand . . .)" and "may be dispensed to any appropriate material, such as an applicator/device/wand" or "directly to a tissue, such as an eye area tissue, from a dispenser." J.A. 1448 (¶ 66). But nowhere in paragraph 66 does it say that the "applicator/device/wand" used to dispense the composition is a swab connected to an electromechanical device used to contact the eyelid margin. It is not enough for anticipation purposes to say that an "applicator/device/wand" may dispense a composition "directly to . . . an eye area tissue, from a dispenser" where the claims require a swab connected to an electromechanical device used to contact the eyelid margin.

Myco goes on to cite paragraph 75, which states that, "[i]n other embodiments, the composition may be applied to the eyelid and/or eyelash using part of the body, such as a knuckle or finger, or a material (e.g., a pad, sponge, brush, sponge [sic], or swab containing an applicator such as cotton, polyester, rayon, or other material)." J.A. 1448 (¶ 75). According to Myco, paragraph 75 discloses using a swab with the electromechanical device embodiment depicted in Figure 3. But, as the district court found, paragraph 75 expressly refers to "other embodiments," indicating that paragraph 75 describes options for embodiments *other than* that depicted in Figure 3—the only embodiment that includes an electromechanical device. J.A. 1448; *Reconsideration Decision*, 2020 WL 7134932, at *2. We also are not persuaded by Myco's reference to Nichamin's paragraphs 79 and 87. Paragraph 79 states that "[a]ny of these methods of applying the compound may be combined with any other method." J.A. 1448 (¶ 79). Paragraph 87 provides that "it is contemplated that any optional feature of the inventive variations described may be set forth and claimed independently, or in combination with any one or more of the features described herein." J.A. 1449 (¶ 87). These generic statements do not establish that one of skill in the art would "at once envisage" the specific

combination Myco urges. *Chamberlain Grp.*, 935 F.3d at 1350.

Finally, Myco points us to Figure 6 of Nichamin (shown below), which depicts a kit including "an applicator (e.g., pad or swab)." J.A. 1449 (¶ 83). Myco argues that Figure 3's applicator may be a swab because Figure 6's applicator may be a "pad or swab." Again, we are unpersuaded. Nowhere in Figure 6 is there any indication that the swab should be connected to the electromechanical device of Figure 3 and used to contact the eyelid margin. Rather, the swab of Figure 6 appears to be the handheld swab also shown in Figure 1. Paragraph 83 also discloses optional inclusion of a microdermabrasive device in the kit depicted in Figure 6. It does not, however, disclose connecting the swab to that device.

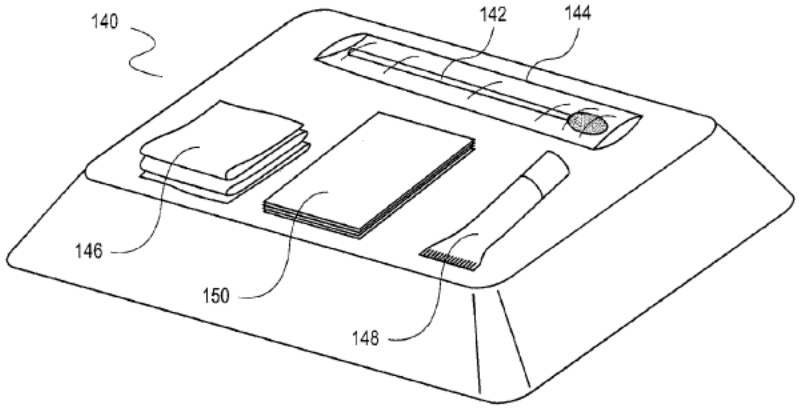

FIG. 6

J.A. 1442.

The district court did not clearly err in finding that "[n]owhere in the text of Nichamin is it suggested the handheld device in Figure 3 includes a swab." *Reconsideration Decision*, 2020 WL 7134932, at *2. None of the paragraphs

identified by Myco on appeal describe a swab that is both operably connected to an electromechanical device and used to contact the eyelid margin, as required by claim 16.

Myco argues that the district court improperly deferred to the patent examiner when it noted that the examiner considered Nichamin during examination and, nevertheless, allowed the '087 patent to issue. That is not the case. To the extent Myco is suggesting that the examiner did not substantively consider Nichamin during prosecution of the '087 patent, and that this alleged failure to consider Nichamin should have some effect on the burdens borne by the respective parties in this case, that argument is unavailing. "[W]hen prior art 'is listed on the face' of a patent, 'the examiner is presumed to have considered it.'" *Stone Basket Innovations, LLC v. Cook Med. LLC*, 892 F.3d 1175, 1179 (Fed. Cir. 2018) (quoting *Shire LLC v. Amneal Pharms., LLC*, 802 F.3d 1301, 1307 (Fed. Cir. 2015)). Because Nichamin is cited on the face of the '087 patent, the patent examiner is presumed to have considered it and the district court did not err in noting that Nichamin was before the examiner. To the extent Myco contends that the district court relied solely on the presumption of validity, it is clear that the district court considered the substantive anticipation arguments presented by Myco and found them unavailing. The district court did not improperly defer to the patent examiner, as Myco claims.

4. Obviousness

Myco's obviousness argument before the district court consisted of only a single sentence appended to its anticipation argument: "In addition, based on Nichamin's description, it would have been obvious to one of ordinary skill in the art to attach a swab to the end of Nichamin's hand-held device." J.A. 1405. Myco offered no evidence in support of this assertion and no additional argument explaining it. In other words, Myco put all of its eggs in the anticipation basket at the preliminary injunction stage.

Having failed to convince the district court that Nichamin anticipates claim 16, Myco now claims it did not need to present any evidence beyond the Nichamin reference itself in support of its obviousness defense.

Specifically, Myco argues that "it would have been common sense" to "use a swab with Nichamin's Figure 3 device," and, thus, that it had no need to present any evidence beyond the reference itself, expert or otherwise, to show a substantial question of obviousness. Appellant's Br. 41. And Myco argues that the district court improperly relied on unsubstantiated safety concerns associated with chafing sensitive eye tissue when it found insufficient evidence of a motivation to combine Nichamin's electro-mechanical device with a swab. We are unpersuaded by Myco's arguments.

As to Myco's first argument, we conclude that the district court did not clearly err in finding that Myco's conclusory obviousness argument did not pose a substantial question of validity. It is true that "[t]he burden on the accused infringer to show a substantial question of invalidity at [the preliminary injunction] stage is lower than what is required to prove invalidity at trial." *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999, 1006 (Fed. Cir. 2009). But Myco failed to present any evidence regarding the factual considerations underlying the obviousness inquiry, including whether a skilled artisan would have been motivated to modify the device of Figure 3 to use a swab.

Generally, expert testimony is not required at the preliminary injunction stage given the lower burden and because the timing of a preliminary injunction may foreclose the possibility of developing "a fully comprehensive presentation of [an accused infringer's] defenses," *New England Braiding Co. v. A.W. Chesterton Co.*, 970 F.2d 878, 883 (Fed. Cir. 1992). And, some cases, even beyond the preliminary injunction stage, "involve technologies and prior art that are simple enough that no expert testimony is

needed." *Intercontinental Great Brands LLC v. Kellogg N. Am. Co.*, 869 F.3d 1336, 1348 (Fed. Cir. 2017).

But this is not a case involving simple technology. Myco repeatedly argues that the level of skill in the art is very high, even going so far as to argue that its burden to show obviousness at trial and at the preliminary injunction stage is lessened because such a high level of skill is required to comprehend the art. Yet Myco presents no evidence of what this highly skilled artisan would be motivated to do beyond conclusory attorney argument. Myco cannot have it both ways. Although Myco need not have presented expert testimony, it needed to provide something on which the district court could base a finding that there is a substantial question of validity. In this case, where the level of skill in the art is so high, conclusory attorney argument is not enough.[4]

As to Myco's second argument, the district court did not clearly err in finding that Myco failed to explain how a skilled artisan would have addressed the safety concerns of its proposed modification. While Myco claims BlephEx overstates the safety concerns that the combination would present, Myco's failure to present evidence of a motivation to modify and failure to rebut BlephEx's evidence of a motivation *not* to modify demonstrates that Myco did not carry its initial burden of showing a substantial question of validity. *See Metalcraft of Mayville, Inc. v. The Toro Co.*,

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[4] The obviousness argument before the district court was so sparse that we might be justified in finding that Myco forfeited the argument. But we need not rely on forfeiture. The inadequacy of the record leads us to the same judgment. Of course, findings of fact and legal conclusions predicated on the record developed at the preliminary injunction stage are not binding on the court at trial. *Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285, 1302 (Fed. Cir. 2012).

848 F.3d 1358, 1367 (Fed. Cir. 2017) (finding that the district court did not abuse its discretion in rejecting the obviousness argument of a party seeking to avoid a preliminary injunction where the party did not provide any evidence as to a motivation to combine prior art references).

For the foregoing reasons, we see no clear error in the district court's determination that Myco failed to show a substantial question of validity and that BlephEx showed a strong likelihood of success on the merits.

B. Status Quo

Myco next argues that the purpose of a preliminary injunction is to preserve the status quo and that, here, the preliminary injunction upset the status quo. Myco also maintains that the district court never addressed its arguments concerning preservation of the status quo. We disagree.

At the outset, we note that Myco misidentifies the "status quo" in this case. Myco posits that the "status quo" is the last uncontested status preceding the start of the parties' controversy. It asserts that, in this case, the "status quo" is the state of the world before the '087 patent issued, i.e., "a market where both BlephEx and Myco competed and sold their products" and in which BlephEx could not assert infringement of claim 16, as it had not yet been granted. Appellant's Br. 26–27. Although the '087 patent was granted after Myco began selling the AB Max, it was granted before BlephEx filed suit against Myco, even if only shortly before. Thus, the status quo when the preliminary injunction was filed was a state in which the '087 patent had been granted and could be asserted.

Contrary to Myco's arguments, moreover, preservation of the status quo is not the sole objective of preliminary injunctions. Preliminary injunctions also serve to prevent ongoing trespasses during the pendency of an infringement case. *See Atlas Powder Co. v. Ireco Chems.*, 773 F.2d 1230,

1232 (Fed. Cir. 1985) ("[A] preliminary injunction preserves the status quo if it prevents future trespasses."). Even where a patent is applied for and granted after the allegedly infringing product enters the market, a preliminary injunction may still be used to prevent future trespasses on the patent, so long as the district court correctly applies the relevant factors. After all, "there is nothing improper, illegal, or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market." *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988). Any such application, "must comply with all statutes and regulations, of course, but, if it does, its genesis in the marketplace is simply irrelevant and cannot of itself evidence deceitful intent." *Id. (citing State Indus., Inc. v. A.O. Smith Corp.,* 751 F.2d 1226, 1235 (Fed. Cir. 1985)).[5] And patents so obtained are generally entitled to all the same enforcement rights as every other patent.

Just as preservation of the status quo is not the sole aim of preliminary injunctions, it is not an overriding concern that trumps consideration of the four preliminary injunction factors. Rather, it is inherent in the four preliminary injunction factors—particularly in the "irreparable harm" and "balance of hardships" factors. In some cases, a preliminary injunction may rightly disturb the status quo.

Contrary to Myco's assertion that the district court ignored the status quo, the district court considered the status quo in its analysis of the irreparable harm factor. We do not discern clear error in that analysis. Nor do we believe that the district court gave short shrift to its consideration of the status quo. The district court directly

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[5] Of course, an applicant also must comply with 35 U.S.C § 115, which requires a declaration that the individual believes him or herself to be the original inventor.

addressed Myco's claim that the allegedly infringing sales of the AB Max had occurred before issuance of the '087 patent. It found that the record showed that Myco and BlephEx are direct competitors, that BlephEx had suffered price erosion, loss of goodwill, and damage to its reputation, and that BlephEx is threatened with extinction by continued sales of the AB Max. In response to Myco's assertion that all evidence of confusion, price erosion, and loss of goodwill predated issuance of the '087 patent, the district court pointed to Myco's continued efforts to market and sell the AB Max after the patent issued. The district court also identified an email from after the patent issued in which a BlephEx customer complained that they did not want to pay double for the same product. The district court did not clearly err in finding that these facts were "sufficient evidence to establish ongoing irreparable harm" to BlephEx "when considered in conjunction with the significant evidence of pre-issuance loss of goodwill and sales along with price erosion." *Preliminary Injunction Decision*, 2020 WL 5951504, at *7. Thus, the district court appropriately considered the status quo in its analysis.

C. Scope of the Preliminary Injunction

Myco argues that the preliminary injunction is overbroad because it enjoins all domestic sales of the AB Max product even though BlephEx's patent only covers a single method of use. Myco argues that the injunction should only bar "Myco from instructing or encouraging users to use the AB Max to contact the eyelid margin to remove debris." Appellant's Br. 50. In furtherance of this argument, Myco asserts that it presented evidence of potentially non-infringing uses of the AB Max. Finally, Myco argues that the district court erred in placing the burden on Myco to identify potentially non-infringing uses of the AB Max when the burden should have been on BlephEx to argue that the AB Max had no non-infringing use.

We review challenges to the scope of a preliminary injunction under the standard of review used in the regional circuit. *Allergan, Inc. v. Athena Cosms., Inc.*, 738 F.3d 1350, 1354 (Fed. Cir. 2013). The Sixth Circuit reviews the scope of an injunction for an abuse of discretion. *Audi AG v. D'Amato*, 469 F.3d 534, 550 (6th Cir. 2006).

The district court did not abuse its discretion when it barred all domestic sales of the AB Max. Ample evidence supports a finding that an injunction against all sales of the AB Max product is necessary to avoid future infringement. The two expert declarations that Myco avers present evidence of potentially non-infringing uses of the AB Max do not indicate that the device has ever actually been so used. And, as the district court found, those declarations are contradicted by other expert testimony. For example, Myco's expert's statement that the AB Max could be used without contacting the eyelid margin was contradicted by testimony from BlephEx's expert that, due to the size of the AB Max swab, the device could not practically be used to contact only eyelashes without also contacting the eyelid margin. And Myco's expert's statement that the AB Max could be used in a non-infringing manner to treat conjunctiva was contradicted by another of Myco's experts, who had previously indicated that use of the AB Max to contact conjunctiva would cause harm. On top of these contradictions, as the district court noted, the AB Max is registered with the FDA as a device that "cleanses the eyelid margins." *Reconsideration Decision*, 2020 WL 7134932, at *4. And "AB" in AB Max stands for "anterior blepharitis," indicating that the device is designed for a use that the district court found likely to infringe—treating anterior blepharitis—rather than other, potentially non-infringing, uses. *Id.* Taken together, nothing in the district court's analysis indicates an abuse of discretion.

We find Myco's assertion that the district court placed the burden on Myco to show non-infringing uses similarly unavailing. The district court did not place the burden on

Myco to show non-infringing uses. Rather, it weighed the evidence presented by both sides, including evidence belatedly produced by Myco, and determined that its preliminary injunction was not overbroad.

III. CONCLUSION

For the foregoing reasons, we affirm.

AFFIRMED