

UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA

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CIVIL MINUTES - GENERAL

CASE NO.: CV 16-07749 SJO (PJWx) DATE: April 26, 2018

TITLE: Akeso Health Sciences, LLC v. Designs for Health, Inc.

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**PRESENT: THE HONORABLE S. JAMES OTERO, UNITED STATES DISTRICT JUDGE**

Victor Paul Cruz Not Present  
Courtroom Clerk Court Reporter

**COUNSEL PRESENT FOR PLAINTIFF: COUNSEL PRESENT FOR DEFENDANT:**

Not Present Not Present

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**PROCEEDINGS (in chambers): ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT [Docket No. 58]**

This matter is before the Court on Defendant Designs for Health, Inc.'s ("DFH" or "Defendant") Motion for Summary Judgment ("Motion"), filed March 19, 2018. Plaintiff Akeso Health Sciences, LLC ("Akeso" or "Plaintiff") opposed the Motion ("Opposition") on April 9, 2018. The Court found this matter suitable for disposition without oral argument and vacated the hearing set for April 30, 2018. See Fed. R. Civ. P. 78(b). For the following reasons, the Court **GRANTS** the Motion.

I. FACTUAL AND PROCEDURAL BACKGROUND

Akeso initiated the instant patent infringement action against DFH on October 18, 2016, alleging that DFH's Migranol™ product indirectly infringes claims of U.S. patent No. 6,500,450 (the "'450 Patent"). (See Compl. ¶¶ 1, 6, 8, ECF No. 1.) Pursuant to a stipulation between the parties, Akeso filed a First Amended Complaint ("FAC") on January 20, 2017. (See FAC, ECF No. 23.) The FAC identifies Akeso's founder, Curt Hendrix ("Hendrix"), as the sole inventor of the '450 Patent and Akeso as the owner by assignment. (FAC ¶¶ 9-10.)

The '450 Patent, titled "Composition for Treating Migraine Headaches," relates to a dietary supplement for the treatment of migraine headache. (FAC Ex. A ("'450 Patent") at Abstract, ECF No. 23-1.) Akeso sells products under the MigreLief® brand that practice claims of the '450 Patent and marks its MigreLief® products and its website with this patent number. (FAC ¶¶ 13-14, 26.) DFH manufactures and sells the migraine treatment product Migranol, which Akeso accuses of indirectly infringing certain claims of the '450 Patent due to various instructions and implications on the label. (See FAC ¶¶ 15, 17.)

On April 18, 2006, Hendrix's attorney sent a letter to DFH in which he informed DFH of Hendrix's ownership of the '450 Patent and demanded that, due to the "similarity" between Migranol and the compositions of the patent, DFH "cease manufacture and/or distribution of [Migranol], remove the inventory of [Migranol] from any stores in which you have placed the product, destroy all inventory

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and returned product labeled as [Migranol] and provide our office with written confirmation of your specific actions in these regards by the close of business on May 1, 2006." (Decl. David R. Pegnataro in Supp. Mot. ("Pegnataro Decl.") Ex. 15 ("Cease and Desist Letter"), ECF No. 58-16.) On April 27, 2006, an attorney for DFH responded that "due to the nature of this matter, we unavoidably require some additional time to fully analyze the two patents above, discuss the issue with our client, and communicate to you our response." (Pegnataro Decl. Ex. 16 ("Response Letter"), ECF No. 58-17.) DFH's attorney added that "[w]e will be in contact with you with our response no later than 12 May 2006," providing his contact information should Hendrix "wish to discuss this matter further." (Response Letter 1.) No further communications were exchanged between the parties until Akeso filed this action on October 18, 2016. (Pl's Statement of Genuine Disputes of Material Fact ("SGDMF") ¶ 7, ECF No. 66.)

II. DISCUSSION

DFH makes three arguments in the Motion. First, Akeso is equitably estopped from asserting the '450 Patent due to its ten (10) year delay in filing suit. (Mot. 3-8, ECF No. 68.) Second, the asserted claims of the '450 Patent are invalid due to obviousness and lack of enablement. (Mot. 9-18.) Third, Akeso may not recover its lost profits because it is neither the exclusive licensee nor valid owner of the '450 Patent. (Mot. 18-20.) Because the Court finds that Akeso is equitably estopped from asserting its claims, the Court does not reach DFH's second and third arguments.

A. Legal Standards

1. Summary Judgment

Federal Rule of Civil Procedure 56(a) mandates that "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party bears the initial burden of establishing the absence of a genuine issue of material fact. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). "When the party moving for summary judgment would bear the burden of proof at trial, it must come forward with evidence which would entitle it to a directed verdict if the evidence went uncontroverted at trial. In such a case, the moving party has the initial burden of establishing the absence of a genuine issue of fact on each issue material to its case." *C.A.R. Transp. Brokerage Co. v. Darden Rests., Inc.*, 213 F.3d 474, 480 (9th Cir. 2000) (citations omitted). In contrast, when the nonmoving party bears the burden of proving the claim or defense, the moving party does not need to produce any evidence or prove the absence of a genuine issue of material fact. *See Celotex*, 477 U.S. at 325. Rather, the moving party's initial burden "may be discharged by 'showing'—that is, pointing out to the district court—that there is an absence of evidence to support the nonmoving party's case." *Id.* "Summary judgment for a defendant is appropriate when the plaintiff 'fails to make a showing sufficient to establish the existence of an element essential to [his] case, and on which [he] will bear the burden of proof at trial.'" *Cleveland v. Policy Mgmt. Sys. Corp.*, 526 U.S. 795, 805-06 (1999) (quoting *Celotex*, 477 U.S. at 322).

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Once the moving party meets its initial burden, the "party asserting that a fact cannot be or is genuinely disputed must support the assertion." Fed. R. Civ. P. 56(c)(1). "The mere existence of a scintilla of evidence in support of the [nonmoving party]'s position will be insufficient; there must be evidence on which the jury could reasonably find for the [nonmoving party]." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986); accord *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986) ("[O]pponent must do more than simply show that there is some metaphysical doubt as to the material facts."). Further, "[o]nly disputes over facts that might affect the outcome of the suit . . . will properly preclude the entry of summary judgment [and f]actual disputes that are irrelevant or unnecessary will not be counted." *Liberty Lobby*, 477 U.S. at 248. At the summary judgment stage, a court does not make credibility determinations or weigh conflicting evidence. See *id.* at 249. A court is required to draw all inferences in a light most favorable to the nonmoving party. *Matsushita*, 475 U.S. at 587.

2. Equitable Estoppel

The applicability of equitable estoppel is "committed to the sound discretion of the trial judge." *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1042 (Fed.Cir.1992) (en banc). "Three elements are required for equitable estoppel to bar a patentee's suit: (1) the patentee, through misleading conduct (or silence), leads the alleged infringer to reasonably infer that the patentee does not intend to enforce its patent against the alleged infringer; (2) the alleged infringer relies on that conduct; and (3) the alleged infringer will be materially prejudiced if the patentee is allowed to proceed with its claim." *Radio Sys. Corp. v. Lalor*, 709 F.3d 1124, 1130 (Fed. Cir. 2013). "Misleading conduct occurs when the alleged infringer is aware of the patentee or its patents, and knows or can reasonably infer that the patentee has known of the allegedly infringing activities for some time." *High Point SARL v. Sprint Nextel Corp.*, 817 F.3d 1325, 1330 (Fed. Cir. 2016) (citing *Aukerman*, 960 F.2d at 1042). Equitable estoppel "applies to successors-in-interest where privity has been established." *Radio Sys.*, 709 F.3d at 1131.

For silence to be misleading, it "must be accompanied by some *other* factor which indicates that the silence was sufficiently misleading as to amount to bad faith." *Hemstreet v. Computer Entry Sys. Corp.*, 972 F.2d 1290, 1295 (Fed. Cir. 1992) (emphasis in original). "In the cases that have applied intentionally misleading silence in the patent infringement context, a patentee threatened immediate or vigorous enforcement of its patent right but then did nothing for an unreasonably long time." *Meyers v. Asics Corp.*, 974 F.2d 1304, 1309 (Fed. Cir. 1992) (citations and quotations omitted). "In deciding whether to bar the suit on estoppel grounds, the court must consider all evidence relevant to the equities." *Aspex Eyewear Inc. v. Clariti Eyewear, Inc.*, 605 F.3d 1305, 1310 (Fed. Cir. 2010)

B. Analysis

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1. Ten-year Silence on Infringement Qualifies as Misleading Conduct

The parties do not dispute that neither Akeso nor Hendrix took any affirmative steps to mislead DFH as to its intentions; the sole question is whether the ten-year silence after Hendrix issued his cease-and-desist letter, alone, is sufficiently misleading as to provide a basis for equitable estoppel. In this analysis, the Federal Circuit's decisions in *Hemstreet* and *Aspex* are instructive.

In *Hemstreet*, the plaintiff sent the defendant a letter in which it: (1) offered to negotiate a license; (2) mentioned other litigation and licensees; (3) provided information about a pending lawsuit against another member of the defendant's industry; and (4) requested that the defendant contact the plaintiff after studying the patents. *Hemstreet*, 972 F.2d at 1292. The defendant responded that it would examine the patents, and promised to inform the plaintiff of its findings. *Id.* The defendant also requested and was provided with further information about licensing. *Id.* No further communication occurred until 1989, when the plaintiff contacted the defendant with a proposed tolling agreement. *Id.*

The Federal Circuit found that the six year silence was not misleading as, since "license negotiations were underway," the parties "were not in an adversarial stance," and therefore the plaintiff "has less reason to be vigilant in pressuring [the defendant] for a response." *Id.* at 1295. The Federal Circuit noted that at the time the communication lapsed, the "onus" was upon the defendant to communicate with the plaintiff, not the reverse. *Id.* Thus, any "inaction" was attributable to the defendant, not the plaintiff. *Id.*

In *Aspex*, the plaintiff sent the defendant two separate cease-and-desist letters in which it stated that "some of the products sold by you may be covered by the claims of the above mentioned patents" and asked the defendant "to immediately confirm for us that you have stopped selling any [products] in violation of our rights under the patent[s]." *Aspex*, 605 F.3d at 1308. In response to further communication from the plaintiff regarding the file history and specific infringement allegations of two of the three patents mentioned in the cease-and-desist letters, the defendant responded that it did not believe their products infringe any valid claims of the two patents. *Id.* at 1309. No further communication happened between the parties concerning the third patent until three years later. *Id.* The Federal Circuit upheld the district court's finding of equitable estoppel, finding that the correspondence was reasonably viewed by the defendant "as a threat of an infringement suit" and thus the three ensuing years was an unreasonable delay in enforcement. *Id.* at 1311.

Taken together, these cases suggest that in order for a period of silence to be construed as misleading, the initial contact leading to silence must be "adversarial" in that it can be reasonably viewed "as a threat of an infringement suit" rather than a "license negotiation." *See Hemstreet*, 972 F.2d at 1295, *Aspex* 605 F.3d at 1311; *see also Meyers*, 974 F.2d at 1309 ("In the cases that have applied intentionally misleading silence in the patent infringement context, a patentee

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threatened immediate or vigorous enforcement of its patent right but then did nothing for an unreasonably long time."). Here, the language of the cease-and-desist letter mirrors *Aspex* far more than it does *Hemstreet*; Hendrix demands that DFH immediately cease manufacture and distribution of the accused product as well as destroy all of its current inventory. (Cease and Desist Letter 1.) At no point in the letter does Hendrix suggest that licensing is a possibility. There is simply no plausible interpretation that Hendrix's position was non-adversarial; the threat of litigation was implied heavily throughout, even if not explicitly stated. See *Aspex*, 605 F.3d at 1311 (holding that a letter does not need to explicitly state that litigation is threatened to be reasonably viewed as indicating such a threat).

Given that the letter constituted a threat of litigation for the purposes of finding a misleading silence, the question then becomes whether the delay in filing suit constituted an "unreasonably long time." *Meyers*, 974 F.2d at 1309. Akeso again points to *Hemstreet* for the proposition that, at the time the communications were concluded, the "onus" was on DFH to respond to its letter, and thus it had no obligation to maintain communications. (Opp'n 7, ECF No. 65.) As noted above, however, the Federal Circuit's holding rested in large part on its finding that the initial communications in *Hemstreet* were "non-adversarial." When DFH failed to meet its own extended deadline, Hendrix chose not to follow up on his threats. This decision could have been interpreted by DFH, after a reasonable period of time, as a relinquishment of Hendrix's infringement claims.

This finding is further bolstered by the fact that the suit for infringement was delayed for over **ten** years. Under 35 U.S.C § 286, a patentee cannot recover for "any infringement committed more than six years prior to the filing of the complaint." Once six years had passed, the patentee would no longer have been able to recover for the allegedly infringing conduct that had occurred at the time the letter was issued. Given that there is nothing on the record that would support an inference by DFH that the delay was tactical in nature, see *Aukerman*, 960 F.2d at 1044 (finding that there was a question of fact as to whether the plaintiff failed to sue because the defendant had informed it that any potential recovery at that time would be *de minimis*), the patentee's failure to preserve over four years' worth of potential lost profits is reasonably interpreted as an abandonment of its claims. Thus, the Court finds that "the patentee, through misleading conduct (or silence), [led] the alleged infringer to reasonably infer that the patentee [did] not intend to enforce its patent against the alleged infringer[.]" *Radio Sys.*, 709 F.3d at 1130.

2. DFH has Adequately Demonstrated Reliance

DFH must next show that it detrimentally "relied" on the misleading silence. Detrimental reliance is successfully demonstrated if the defendant can show that it "would have acted differently if the threat of litigation was a possibility." *High Point*, 817 F.3d at 1325. DFH's Chairman, Jonathan Lizotte, submitted a declaration averring that if Hendrix had diligently pursued his claim of infringement, DFH would have considered modifying Migranol's labeling and/or composition to avoid DFH's claims or directing its investment, marketing, production and sales efforts into other

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products.<sup>1</sup> (Decl. Jonathon Lizotte in Supp. Mot. ("Lizotte Decl.") ¶¶ 17-18, ECF No. 62.) Instead, because DFH believed that Hendrix had abandoned his claim of infringement, DFH chose to continue selling and marketing Migranol and increased its investment in Migranol over the ten-year period. (Lizotte Decl. ¶¶ 11, 15.)

Akeso argues only that DFH's evidence does not demonstrate that it invested in Migranol in reliance on Akeso's conduct because "its sales of Migranol remained at about the same relatively low level from 2006 through 2010," increasing in substantial part between 2012 and 2017. (Opp'n 8, Lizotte Decl. ¶ 16.) As explained above, however, an inference of abandonment would have been substantially bolstered after six years had passed from Akeso's threat of infringement. Contrary to Akeso's arguments, the longer DFH waited to invest in Migranol, the stronger its claim of reliance may be. Akeso has therefore failed to demonstrate that DFH's evidence regarding reliance was improper, and the Court finds that DFH has adequately demonstrated reliance.

3. DFH has Adequately Demonstrated Prejudice

DFH must finally demonstrate that it will be "materially prejudiced if the patentee is allowed to proceed with its claim." *Radio Sys.*, 709 F.3d at 1130. "Prejudice may be shown by a change of economic position flowing from actions taken or not taken by the patentee." *Aspex*, 605 F.3d at 1312. In the six years leading up to Akeso's suit, DFH's marketing and investment efforts in Migranol yielded sales that nearly quadrupled its revenue. (See Lizotte Decl. ¶ 16.) Rather than demonstrate that the investment was "simply a business decision to capitalize on a market opportunity," as Akeso claims, these facts indicate more strongly that **Akeso** saw a market opportunity to resuscitate its previously abandoned claims in order to capitalize on DFH's stronger revenues. (See Opp'n 9.) After ten years of failing to follow up on its threat of infringement, DFH would be undeniably prejudiced if the Court allowed Akeso to bring forth its claims only after DFH made substantial investments in its product.

IV. RULING

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<sup>1</sup> Akeso objects to Lizotte's declaration as speculative and conclusory. (See Objections to Evidence at 3, ECF No. 70.) The Federal Circuit rejected a similar challenge to declaration testimony regarding reliance in *Aspex*, finding that the defendant "need not prove precisely what alternative paths it would have taken, or that every marketing decision was based on reliance on Aspex's silence." *Aspex*, 605 F.3d at 1312. Like in *Aspex*, DFH has provided evidence supporting plausible actions it would have taken had it been faced with a threat of infringement and actions it affirmatively took in the absence of that threat; DFH is not required to prove a negative. Accordingly, Akeso's objection is **OVERRULED**.

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For the foregoing reasons, the Court **GRANTS** Defendant Designs for Health, Inc.'s Motion for Summary Judgment. Defendant shall lodge a proposed judgment within seven (7) days of the date of this Order.

IT IS SO ORDERED.