IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOVERATIV INC., BIOVERATIV THERAPEUTICS INC., and BIOVERATIV U.S. LLC,

Plaintiffs,

v.

CSL BEHRING LLC, CSL BEHRING GMBH, and CSL BEHRING LENGNAU AG,

Defendants.

Civil Action No. 17-914-RGA

MEMORANDUM OPINION

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March 23, 2020

ANDREWS, UNITED STATES DISTRICT JUDGE:

Before me are five motions submitted by Bioverativ and CSL Behring. This memorandum opinion will address Defendants' Motion for Summary Judgment of No Willful Infringement or Enhanced Damages. (D.I. 211). I have reviewed the parties' briefing and related papers. (D.I. 217, 227, 237). I heard oral argument on February 21, 2020. After full consideration of the briefing, I will grant Defendants' motion.

I. BACKGROUND

Plaintiffs Bioverativ Inc., Bioverativ Therapeutics Inc., and Bioverativ U.S. LLC filed this lawsuit against Defendants CSL Behring LLC, CSL Behring GmbH, and CSL Behring Lengau AG on July 7, 2017, asserting infringement of U.S. Patent Nos. 9,670,475 ("the '475 patent"), 9,623,091 ("the '091 patent"), and 9,629,903 ("the '903 patent") (collectively, "the Asserted Patents"). (D.I. 1).

Plaintiffs assert that Defendants infringe claims 1 and 24 of the '091 patent, claims 1 and 22 of the '903 patent and claims 1, 12, 14, 17, 18, 19, and 29 of the '475 patent. (D.I. 1). All claims of the three patents are method claims.

Independent claim 1 of the '091 patent is as follows:

> A method of treating hemophilia B in a human subject in need thereof comprising intravenously administering to the subject multiple doses of about 50 IU/kg to about 100 IU/kg of a chimeric factor IX ("FIX") polypeptide comprising FIX and an FcRn binding partner ("FcRn BP") at a dosing interval of about 10 days to about 14 days between two doses, wherein the FcRn BP comprises Fc or albumin, wherein the administration maintains the plasma FIX activity of the subject above 1 IU/dL between the dosing interval, and wherein the administration treats the human subject by reducing the frequency of spontaneous bleeding.

(D.I. 221-1, Exh. 2 at 79:25-36). Claim 1 of the '903 patent and Claim 1 of the '475 patent are similar but provide other FIX activity ('903 patent) and dosing intervals and amounts ('475

patent). Idelvion, the accused product, is a chimeric FIX polypeptide that comprises FIX and albumin as its FcRn binding partner. (D.I. 217 at 2).

Defendants move for summary judgment of no willfulness or enhanced damages. (D.I. 211).

II. LEGAL STANDARD

"The 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 has the initial burden of proving the absence of a genuinely disputed material fact relative to the claims in question. *Celotex Corp. v. Catrett*, 477 U.S. 317, 330 (1986). If the moving party has demonstrated an absence of material fact, the nonmoving party then "must come forward with 'specific facts showing that there is a genuine issue for trial.'" *Solvay, S.A. v. Honeywell Specialty Materials LLC*, 827 F.Supp.2d 358, 361-62 (D. Del. 2011), citing *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986) (quoting Fed. R. Civ. P. 56(e)). Material facts are those "that could affect the outcome" of the proceeding, and "a dispute about a material fact is 'genuine' if the evidence is sufficient to permit a reasonable jury to return a verdict for the nonmoving party." *Lamont v. New Jersey*, 637 F.3d 177, 181 (3d Cir. 2011) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). When determining whether a genuine issue of material fact exists, the court must view the evidence in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor. *Scott v. Harris*, 550 U.S. 372, 380 (2007); *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007).

III. DISCUSSION

a. Willful Infringement

As the Supreme Court stated in *Halo*, "[t]he sort of conduct warranting enhanced damages has been variously described in our cases as willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or—indeed—characteristic of a pirate." *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923, 1933 (2016). While district courts have discretion in deciding whether or not behavior rises to that standard, such findings "are generally reserved for egregious cases of culpable behavior." *Id.* A patentee need only show by a preponderance of the evidence the facts that support a finding of willful infringement. *Id.* at 1934.

The concept of "willfulness" requires a jury to find no more than deliberate or intentional patent infringement. *Id.* at 1933 ("The subjective willfulness of a patent infringer, intentional or knowing, may warrant enhanced damages, without regard to whether his infringement was objectively reckless."); *SRI Int'l, Inc. v. Cisco Sys.*, 930 F.3d 1295, 1308 (Fed. Cir. 2019). The question of enhanced damages is addressed by the court once an affirmative finding of willfulness has been made. *See Halo*, 136 S. Ct. at 1933-34. It is at this second stage at which the considerations of egregious behavior and punishment are relevant. *Eko Brands, LLC v. Adrian Rivera Maynez Enters., Inc.*, 946 F.3d 1367 (Fed. Cir. 2020)

There can be no willful infringement before a patent is issued. "It is obvious that a party cannot be held liable for 'infringement,' and thus not for 'willful' infringement of a *nonexistent* patent, i.e., no damages are payable on products manufactured and sold before the patent issued." *Gustafson, Inc. v. Intersys. Indus. Prods., Inc.*, 897 F.2d 508, 510 (Fed. Cir. 1990) "[A]lthough willfulness is generally based on conduct that occurred after a patent issued, pre-patent conduct may also be used to support a finding of willfulness." *Minnesota Min. & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1581 (Fed. Cir. 1992) (willfulness finding properly rested in part on actions to misappropriate trade secrets prior to issuance of patent). Pre-patent

copying of the invention, for example, is relevant to the defendant's state of mind after issuance. *Milgo Elec. Corp. v. United Bus. Commc'ns, Inc.*, 623 F.2d 645, 665-66 (10th Cir. 1980). Plaintiffs argue that evidence of pre-issuance conduct is admissible to show post-issuance willfulness. (D.I. 227 at 22).

Two cases from this district are instructive in suggesting the generally limited relevance of pre-patent-issuance conduct in determining willfulness. In *Idenix Pharm. LLC v. Gilead Sciences, Inc.*, the Court was not "persuaded that the law absolutely precludes pre-patent conduct from being probative of willfulness." 2016 WL 7380530, at *1 (D. Del. Dec. 4, 2016). In *Chimie v. PPG Indus., Inc.*, the Court noted that "in general, only behavior occurring after a patent is issued is relevant to a willfulness inquiry," while allowing that, "particularly egregious behavior showing a party intent on misappropriating a competitor's proprietary technology" would be relevant. 218 F.R.D. 416, 421-22 (D. Del. 2003); *see also State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1238 (Fed. Cir. 1985) (distinguishing *Milgo Elec. Corp.*, in which evidence of pre-issuance copying was admitted due to egregious circumstances that the Federal Circuit described as "a most elaborate and detailed copying . . . by a corps of engineers working in secrecy over a period of a couple of years to pry loose the secret of Milgo's inventions."); *Stryker Corp. v. Davol, Inc.*, 75 F. Supp. 2d 748, 750 (W.D. Mich. 1999) ("Davol's undisputed pre-patent copying is probative of willfulness, but should not be given undue weight.").

To determine whether willful infringement has occurred, the correct inquiry is the "subjective willfulness" of the infringer. *Halo*, 136 S. Ct. at 1933. Plaintiffs allege that Defendants "began confidential discussions with [Bioverativ predecessor] Syntonix to co-develop and manufacture Syntonix's half-life extended Factor IX technology," in June 2005. (D.I. 227 at 23). Plaintiffs allege that by March 2007, Defendants had developed a product

proposition for what would later become Idelvion that "targeted the same once-a-week dosing that Syntonix had disclosed in confidence." (*Id.* at 25). Plaintiffs contend that the evidence will establish at trial that Defendants would not have developed Idelvion without its access to Syntonix's confidential information and without Defendants' collaborative relationship with Syntonix prior to independent development of Idelvion, thereby demonstrating Defendants' willful infringement. (*Id.*). To be clear, Idelvion itself is not accused of infringing any patent, as the three asserted patents only have method of treatment claims. The complained-of development activities all appear to have taken place before the asserted patents' priority date of July 9, 2010, and nearly a decade before the three asserted patents issued in 2017. (D.I. 218, Exhs. 1-3).

Plaintiffs also state that Defendants "closely tracked" Phase III clinical data from Bioverativ predecessor Biogen during the development of Idelvion, and "attempted to match Biogen's dosing interval." (D.I. 227 at 25). They cite Defendants' activities in 2012. (*See* D.I. 228-3, Exh. 18; D.I. 229-2, Exh. 37). The cited documents do not show copying. What they show, at most, is that Defendants wanted to know how Plaintiffs' clinical trials were going. This is not "copying." It is competitive intelligence gathering.

Copying a product which is not protected by the patent laws is not illegal and does not constitute infringement. *Sonos, Inc. v. D&M Holdings Inc.*, 2017 WL 5633204, at *3 (D. Del. Nov. 21, 2017) (citing *Milgo Elec. Corp.*, 623 F.2d at 666). Part of the inquiry when determining willful infringement is whether or not the alleged infringer "acted consistently with the standards of behavior for its industry." Federal Circuit Bar Association, *Model Patent Jury Instructions*, July 2016; *see Eko*, 946 F.3d at 1377-80. Plaintiffs conceded at oral argument that competitive intelligence is standard in the pharmaceutical industry. There are no additional facts before me that suggest that Defendants' pre-patent surveillance activities, including tracking Biogen's

product development and dosing intervals, amounts to "elaborate copying" as in *Milgo* or other "consciously wrongful," "malicious" behavior. *See Halo*, 136 S. Ct. at 1933.

As to Defendants' conduct after the asserted patents issued, the record similarly does not establish that Defendants' conduct rose to the level of wanton, malicious, and bad-faith behavior required for willful infringement. *See id.* at 1932; *SRI Int'l*, 930 F.3d at 1309 (willful infringement requires "wanton, malicious, and bad-faith behavior"). The Food and Drug Administration approved Idelvion in March 2016. (D.I. 217 at 21). Idelvion launched in March 2016. The Asserted Patents issued in April and June 2017. (D.I. 218, Exhs. 1-3). Plaintiffs filed complaints for infringement in the International Trade Commission ("ITC") and this Court in July 2017. *See* D.I. 1; D.I. 8, Exh. 16. Thus, at the time Idelvion was launched, it infringed none of the asserted patents. And, for more than a year after launch, it could not even be asserted that Idelvion infringed any of the asserted patents because they had not issued.

In *Halo*, the Supreme Court noted that "culpability is generally measured against the knowledge of the actor at the time of the challenged conduct." 136 S. Ct. at 1933. This proposition is generally easy to apply in most litigation, but it is not so easy to apply in patent litigation. There was no willfulness as a matter of law from March 2016 until April 2017 when the first of the patents issued. Most torts do not continue while the litigation related to them proceeds. Not so in patent cases, where the usual course is that the defendant keeps on selling the accused product or practicing the accused method after the lawsuit is filed. Thus, as here, there is no colorable willfulness case based on the present record (which includes no evidence of anything occurring between when the first patent issued in April 2017 and when the lawsuit was filed in July 2017). Thus, if there were to be willfulness, it would have to be based on what has happened since the lawsuit was filed.

Since the time the lawsuit was filed, there has been litigation. On January 30, 2018, the Administrative Law Judge presiding over the ITC investigation adopted Defendants' proposed claim constructions and issued a *Markman* ruling that rendered the Asserted Claims of the '475 and the '903 patents "nonsensical." (D.I. 219-1, Exh. 31). A week later, Plaintiffs withdrew their complaint and terminated the ITC investigation. (*Id.*, Exh. 32). Before *Halo*, this would have been considered evidence of the reasonableness of Defendants' non-infringement defenses. But the Supreme Court considered this to "aggravate[] the problem by making dispositive the ability of the infringer to muster a reasonable . . . defense at the infringement trial." *Halo*, 136 S. Ct. at 1933. The Court noted that "such a defense insulates the infringer from enhanced damages, even if he did not act on the basis of the defense or was even aware of it." *Id.* The Court considered this to be bad because "culpability is generally measured against the knowledge of the actor at the time of the challenged conduct," without seeming to consider that in most patent cases, the litigation defenses are going on at the same time as the challenged conduct. *Id.*

Further complicating the matter is the usual practice of relying upon litigation counsel and/or in-house counsel for the usual corporate defendant's analysis of whether the defendant does or does not have any defenses (reasonable or otherwise) to infringement. *See SRI Int'l*, 930 F.3d at 1309 (citing that failure to use an advice-of-counsel defense is "legally irrelevant" and cannot be used against defendant). Thus, to defend against willfulness when willfulness is based on post-filing activity is very difficult, both theoretically and practically as a matter of trial presentation. Experts cannot testify about a defendant's state of mind. Employees of the defendant often have no basis for testifying about a state of mind since patent infringement and invalidity present legal issues for which the corporation is generally relying upon the advice of counsel. The employees cannot testify without waiving attorney-client privilege. Defendants

cannot rely upon the defenses they actually present at trials (although plaintiffs can argue the weakness of the defenses as a basis for a finding of willfulness). And, for whatever reason, almost no corporation chooses to rely upon an advice of defense counsel. Of course, trial counsel cannot vouch for their client, although in the usual case there is some amount of "evidence" that consists of the back-and-forth between trial counsel both before and after the lawsuit is filed. It makes it difficult for both sides to argue the willfulness issue at trial when willfulness is based on post-filing conduct.

In *WBIP v. Kohler*, the court noted, "[A]s the Supreme Court explained in *Halo*, timing . . . matter[s]. [A party] cannot insulate itself from liability for enhanced damages by creating an (ultimately unsuccessful) invalidity defense for trial after . . . 'plundering' [the] patented technology prior to litigation." 829 F.3d 1317, 1340 (Fed. Cir. 2016). Here, it is undisputed that Defendants knew about the patents when they issued. Such knowledge, however, is a necessary but not sufficient prerequisite to willfulness, and Plaintiffs have nothing else that is evidence that Defendants acted willfully. There is no evidence of inappropriate "deliberate copying of the commercial product of the patent owner before issuance of the patent." *See Nox Medical Ehf v. Natus Neurology Inc.*, 2018 WL 4062626, at *13 (D. Del. Aug. 27, 2018). Nor is there any evidence of the copying of the patented methods.

I thus conclude that summary judgment of no willfulness is appropriate.

b. Enhanced Damages

Where there is no finding of willful infringement, enhanced damages cannot be recovered. *Halo*, 136 S. Ct. at 1930. Because I am granting summary judgment of no willfulness, I will also grant Defendants' motion as to no enhanced damages.

IV. CONCLUSION

For the reasons discussed above, I will grant Defendants' motion for summary judgment as to no willfulness or enhanced damages. An Order consistent with this memorandum opinion will be entered.

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ORDER

For the reasons stated in the accompanying memorandum opinion, **IT IS HEREBY ORDERED** that Defendants' Motion for Summary Judgment of No Willful Infringement or Enhanced Damages (D.I. 211) is **GRANTED**.

Entered this 23 day of March, 2020.

/s/ Richard G. Andrews
United States District Judge