IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SHIRE VIROPHARMA INCORPORATED	:	
	:	**CIVIL ACTION**
Plaintiff,	:	
	:	
v.	:	
	:	**NO. 17-414**
CSL BEHRING LLC and CSL BEHRING GMBH	:	
	:	
	:	
Defendants.	:	

Goldberg, J. **January 8, 2018**

MEMORANDUM OPINION

In the pending case, Plaintiff Shire ViroPharma Incorporated ("Plaintiff") alleges that Defendants CSL Behring LLC and CSL Behring GMBH (collectively, "Defendants") have infringed Plaintiff's U.S. Patent No. 9,616,111 through the development and marketing of Defendants' drug Haegarda®. Defendants move to dismiss Plaintiff's claim of willful infringement. For the following reasons, I will deny the Motion.

I. FACTS ALLEGED IN THE SECOND AMENDED COMPLAINT

The Second Amended Complaint alleges the following:[1]

Hereditary angioedema ("HAE") is a rare genetic disorder causing insufficient natural production of functional or adequate amounts of a protein called C1 esterase inhibitor. This

[1] When determining whether to grant a motion to dismiss, a federal court must construe the complaint liberally, accept all well-pleaded factual allegations in the complaint as true, and draw all reasonable inferences in favor of the plaintiff. Fowler v. UPMC Shadyside, 578 F.3d 203, 211 (3d Cir. 2009). Thus, my recitation of the facts assumes the truth of the factual statements in the Complaint.

protein is needed to help regulate several complex processes involved in immune system function and fibrinolytic system function. Patients suffering from HAE experience symptoms including unpredictable, recurrent attacks of swelling commonly affecting the hands, feet, arms, legs, face, abdomen, tongue, genitals, and larynx. HAE may be treated by administration of a drug containing a C1 esterase inhibitor in order to restore the levels of C1 esterase inhibitor to levels sufficient to prevent or reduce the frequency or severity of HAE attacks. (Second Am. Compl. ("SAC") ¶¶ 10–11.)

Plaintiff, through its corporate affiliates, makes and sells products for the treatment of HAE, including CINRYZE, FIRAZYR, and KALBITOR products. Plaintiff also has other products in development, including those known as SHP616 and SHP643. CINRYZE has been approved by the United States Food and Drug Administration ("FDA") for routine prophylactic treatment of angioedema attacks in adolescent and adult patients with HAE, and is indicated for intravenous treatment. Both FIRAZYR and KALBITOR are approved for subcutaneous administration for treatment of acute attacks of HAE. (Id. ¶¶ 12–16.)

On April 11, 2017, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 9,616,111 (the "'111 patent"), entitled "C1-INH Compositions and Methods for the Prevention and Treatment of Disorders Associated with C1 Esterase Inhibitor Deficiency." The claims of the '111 patent are directed generally to methods "for treating hereditary angioedema (HAE) . . . comprising subcutaneously administering . . . a composition comprising a C1 esterase inhibitor, a buffer selected from citrate or phosphate, and having a PH ranging from 6.5–8.0, wherein the C1 esterase inhibitor is administered at a concentration of at least about 400 U/mL and a dose of at least about 1000 U. . . ." Plaintiff is the owner of all rights, title, and interest in the '111 patent. (Id. ¶¶ 17–18.)

On July 25, 2017, Defendants began U.S. sales of a prophylactic C1 esterase inhibitor treatment for subcutaneous administration. Defendants marketed the new C1 esterase inhibitor product as "HAEGARDA," which received FDA approval on June 22, 2017. On July 25, 2017, Defendants issued a press release announcing the availability of HAEGARDA in the United States. (Id. ¶¶ 20–21.) The HAEGARDA product label instructs, in part, that the drug is a "plasma-derived concentrate of C1 Esterase Inhibitor (Human)" to be used for "routine prophylaxis to prevent Hereditary Angioedema (HAE) attacks in adolescent and adult patients." (Id. ¶ 24.) The label further directs HAEGARDA's self-administration by subcutaneous injection. (Id. ¶ 25.)

Plaintiff initiated this action on April 11, 2017, the same day that the '111 patent issued. It filed its Second Amended Complaint on August 24, 2017, setting forth allegations of direct infringement, inducement of infringement, contributory infringement, and willful infringement. On September 7, 2017, Defendants filed the instant Motion to Dismiss Plaintiff's willful infringement claim. Plaintiff responded on September 21, 2017, and Defendant submitted a reply brief on October 5, 2017.

II. STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 12(b)(6), a defendant bears the burden of demonstrating that the plaintiff has not stated a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6); see also Hedges v. United States, 404 F.3d 744, 750 (3d Cir. 2005). The United States Supreme Court has recognized that "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (quotations omitted). "[T]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice" and "only a complaint that

states a plausible claim for relief survives a motion to dismiss." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. A complaint does not show an entitlement to relief when the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct. Id.

The United States Court of Appeals for the Third Circuit has detailed a three-step process to determine whether a complaint meets the pleadings standard. Bistrian v. Levi, 696 F.3d 352 (3d Cir. 2014). First, the court outlines the elements a plaintiff must plead to state a claim for relief. Id. at 365. Next, the court must "peel away those allegations that are no more than conclusions and thus not entitled to the assumption of truth." Id. Finally, the court "look[s] for well-pled factual allegations, assume[s] their veracity, and then 'determine[s] whether they plausibly give rise to an entitlement to relief.'" Id. (quoting Iqbal, 556 U.S. at 679). The last step is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Id. (quoting Iqbal, 556 U.S. at 679).

Although claims of direct infringement were previously governed by Federal Rule of Civil Procedure 84 and the Appendix of Forms, those rules were abrogated effective December 1, 2015. Raindance Techs., Inc. v. 10x Genomics, Inc., No. 15-150, 2016 WL 927143, at *2 (D. Del. Mar. 4, 2016). It is now well established that both direct and indirect infringement claims are subject to the Twombly/Iqbal standard. IP Commc'n Solutions, LLC v. Viber Media (USA) Inc., No. 16-134, 2017 WL 1312942, at *2 (D. Del. Apr. 5, 2017); RAH Color Techs LLC v. Ricoh USA Inc., 194 F. Supp. 3d 346, 350–51 (E.D. Pa. 2016).

III. DISCUSSION

Pursuant to § 284 of the Patent Act, once infringement has been established, the court "may increase the damages up to three times the amount found or assessed." 35 U.S.C. § 284. In 2016, the Supreme Court abrogated the Federal Circuit's previous two-part test for proving willful infringement. Halo Elecs., Inc. v. Pulse Elecs., Inc., 136 S. Ct. 1923 (2016). "In so doing, the Court invited district courts to exercise discretion in evaluating whether to award enhanced damages under 35 U.S.C. § 284." Progme Corp. v. Comcast Cable Commc'n LLC, No. 17-1488, 2017 WL 5070723, at *12 (E.D. Pa. Nov. 3, 2017). The Supreme Court explained that enhanced damages are "designed as a 'punitive' or 'vindictive' sanction for egregious infringement behavior," commonly described as "willful, wanton, malicious, bad faith, deliberate, consciously wrongful, flagrant, or . . . characteristic of a pirate." Halo Elecs, 136 S. Ct. at 1932. "[C]ulpability is generally measured against the actor's knowledge of the actor at the time of the challenged conduct." Id. at 1933 (citations omitted). A patent infringer's subjective willfulness, whether intentional or knowing, "may warrant enhanced damages, without regard to whether his infringement was objectively reckless." Id. at 1933. The Supreme Court stressed that the award of enhanced damages was discretionary and directed that the court "take into account the particular circumstances" in its determination of whether enhanced damages are appropriate, which has been historically "reserved for egregious cases typified by willful misconduct." Id. at 1933–34.

In support of Plaintiff's willful infringement claim, the Second Amended Complaint alleges:

> Defendants' infringement of the '111 patent has been and continues to be willful. CSL Behring had knowledge of the '111 patent prior to the launch of HAEGARDA. Launching HAEGARDA with knowledge of the '111 patent, with knowledge

> that the use of HAEGARDA in the manner directed by the Defendants necessarily would infringe the '111 patent and without asserting any meaningful challenge to the validity of the '111 patent except by repeating arguments that already had been considered and overcome by the patent office, is egregious conduct. Since at least the filing of the original complaint in this action, Defendants have had actual knowledge of the '111 patent and have known that the use of HAEGARDA by inter alia, doctors, other medical professionals, and/or patients constituted direct infringement of the '111 patent. Despite Defendants' actual knowledge of the '111 patent and the knowledge of underlying direct infringement by the public, Defendants continue to actively instruct, direct, or encourage the public to infringe by making, importing, using, selling and/or offering for sale its HAEGARDA product. Defendants further intend that the public use HAEGARDA in a manner that infringes one or more claims of the '111 patent.

(SAC ¶ 44.)

Defendants seek dismissal of the willful infringement claim, arguing that Plaintiff has only made general allegations of willfulness without articulating how Defendants' behavior was "egregious." Indeed, Defendants' assert that, contrary to Plaintiff's allegations of willfulness, they challenged the validity of the '111 patent more than a month prior to launching its Haegarda product, demonstrating their lack of intent to infringe a valid patent and undercutting Plaintiff's allegation that there was no "meaningful" challenge to the patent. Defendants also argue that the willfulness allegations are not plausible because, despite the fact that Plaintiff filed its original and First Amended Complaint prior to Haegarda's FDA approval, it did not seek a preliminary injunction to stop Defendants from launching Haegarda, meaning Plaintiff cannot now allege that Defendants' allegedly infringing conduct is egregious.

Defendants' argument seems to conflate the standards for pleading willful infringement with the standards for proving willful infringement. Even after Halo, broader allegations of willfulness, without a specific showing of egregiousness, are sufficient to withstand a motion to

dismiss. Bio-Rad Labs Inc. v. Thermo Fisher Scientific Inc., __ F. Supp. 3d __, 2017 WL 438733, at *1 (D. Del. Feb. 1, 2017); DermaFocus LLC v. Ulthera, Inc., 201 F. Supp. 3d 465, 473 (D. Del. 2016); Progme Corp., 2017 WL 507023, at *12. "At the pleading stage, it is not necessary to show that the case is egregious." Bio-Rad Labs, 2017 WL 438733, at *1 (citing Halo Elecs., 136 S. Ct. at 1934 (2016)); see also Bayer Healthcare, LLC v. Baxalta, Inc., No. 16-1122, 2017 WL U.S. Dist. LEXIS 126904, at *3 (D. Del. Aug. 10, 2017) ("At this stage of the litigation . . . Plaintiff need not allege egregiousness.").

The Second Amended Complaint adequately alleges that Defendants had knowledge of the '111 patent and that the use of Haegarda in the manner directed would necessarily infringe the '111 patent. It goes on to state that without regard for that patent, and without a "meaningful challenge" to the '111 patent's validity, Defendants launched Haegarda and continue to instruct that it be used in an infringing manner. Defendants' current challenge to the truthfulness of these allegations are not appropriate considerations on a Rule 12(b)(6) motion to dismiss.[2] Rather, taking these allegations as true, one could plausibly infer that Defendants' launch of Haegarda—despite knowing both that the '111 patent existed and that Haegarda's use would infringe the '111 patent—rose to the level of egregious conduct that could support a finding of willfulness.

[2] The cases cited by Plaintiff in its Motion do not support a contrary outcome. In Varian Med. Sys., Inc. v. Elekta AB, No. 15-871, 2016 WL 3748772, at *8 (D. Del. 2016), for example, the complaint had been filed under pre-Halo elements of a willful infringement claim and failed to satisfy the Halo standard. In Zimmer Surgical, Inc. v. Stryker Corp., No. 16-679, 2017 WL 3736750, at *2 (D. Del. Aug. 30, 2017), the court recognized that allegations of post-filing conduct could support a finding of willfulness, but declined to decide how much factual content is required in such allegations because the plaintiffs in that case had not pled any post-filing factual conduct. Finally, in Princeton Digital Image Corp. v. Ubisoft Entm't SA, No. 13-335 2016 WL 6594076, at *11 (D. Del. Nov. 4, 2016), the complaint, unlike the Second Amended Complaint here, neither showed how the defendant was put on notice of its own willful infringement nor articulated how the defendant's actions during a short, three-month period of time amounted to an "egregious" case of infringement.

Moreover, contrary to Defendants' argument, it was not necessary for Plaintiff to file for a preliminary injunction in order to allege a claim for willful infringement. The Federal Circuit, following Halo, reaffirmed that "there is no 'rigid rule' that a patentee must seek a preliminary injunction in order to seek enhanced damages." Mentor Graphics Corp. v. EVE-USA, Inc., 851 F.2d 1275, 1295–96 (Fed. Cir. 2017). Other courts have followed suit. See, e.g., Depomed, Inc. v. Purdue Pharma L.P., No. 13-571, 2017 WL 438738, at *4 (D.N.J. Jan. 31, 2017) ("[I]t is not necessary for [plaintiff] to file for a preliminary injunction in order to file a second amended complaint with claims of willful infringement); Princeton Digital Image Corp. v. Ubisoft Entm't SA, No. 13-335, 2016 WL 6594076, at *11 n.20 (D. Del. Nov. 4, 2016) (recognizing that "some courts have held that, in light of the overall thrust of Halo, the prior rule proscribing post-complaint willful infringement claims (absent filing of a motion for a preliminary injunction) does not jibe with Halo and should be discarded); but see Dorman Prods., Inc. v. Paccar, Inc., 201 F. Supp. 3d 663, 681 (E.D. Pa. 2016), as amended (Oct. 17, 2016) (citing In re Seagate Tech, LLC, 497 F.3d 1360, 1374 (Fed. Cir. 2007) to hold that "[a]bsent evidence of pre-filing willful infringement, a patentee who does not seek a preliminary injunction may not base a claim for willful infringement solely on the infringer's post-filing conduct.").

While Defendants correctly argue that Plaintiff's failure to seek a preliminary injunction undercuts Plaintiff's claim of willful infringement, such an argument is not dispositive of whether Plaintiff adequately pled willful infringement for purposes of Rule 12(b)(6) review. I have already found that Plaintiff has set forth sufficient facts from which to plausibly infer willful infringement. Defendants' defenses to this claim based on Plaintiff's failure to affirmatively prevent any such infringement are better reserved for a motion for summary judgment.

IV. CONCLUSION

In light of the foregoing, I will deny Defendants' Motion to Dismiss. Defendants shall file an answer to the Second Amended Complaint within twenty days of the Order accompanying this Memorandum.