UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

NOVARTIS VACCINES AND DIAGNOSTICS, INC., NOVARTIS PHARMA AG, and GRIFOLS WORLDWIDE OPERATIONS LIMITED, Plaintiffs, -v- REGENERON PHARMACEUTICALS, INC., Defendant.	18cv2434(DLC) OPINION AND ORDER

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DENISE COTE, District Judge:

Novartis Vaccines and Diagnostics, Inc., Novartis Pharma AG, and Grifols Worldwide Operations Limited ("Novartis") commenced this action on March 19, 2018, against Regeneron Pharmaceuticals, Inc. ("Regeneron"), alleging infringement and willful infringement of patented gene expression technology. This lawsuit is brought over three years after the expiration of the Novartis patent and almost seven years after the Regeneron products first entered the market. On August 3, Regeneron moved to dismiss Novartis's claim for willful infringement. For the reasons that follow, Regeneron's motion is granted.

Background

The following facts are drawn from Novartis's amended complaint ("FAC") and exhibits attached to it. They are construed in favor of Novartis. In 2006, Novartis acquired ownership of United States Patent No. 5,688,688 ("the '688 Patent"), entitled "Vector for Expression of a Polypeptide in a Mammalian Cell." This patent was first issued in 1997 and expired on November 18, 2014. It covers gene expression

technology for the expression of polypeptides in mammalian cells. Gene expression technology is commonly used to manufacture proteins that form the active ingredients of medicines.

Regeneron develops medicines to treat a number of diseases. One such medicine is Eylea®, a vascular endothelial growth factor inhibitor approved to treat Neovascular (Wet) Age-Related Macular Degeneration ("AMD"), Macular Edema Following Retinal Vein Occlusion ("RVO"), Diabetic Macular Edema ("DME"), and Diabetic Retinopathy ("DR") in patients with DME. Regeneron has manufactured, marketed, and sold Eylea® in the United States since November 2011. Another medicine developed and produced by Regeneron is Zaltrap®, which is approved for treatment of patients with metastatic colorectal cancer. Regeneron has manufactured, marketed, and sold Zaltrap® in the United States since August 3, 2012. According to Novartis, both Eylea® and Zaltrap® utilize an identical recombinant fusion protein active ingredient, called aflibercept, that is manufactured using Novartis's patented technology covered by the '688 Patent. Specifically, Novartis alleges that Regeneron uses the Lonza GS Expression System, a proprietary commercial gene expression system developed by third-party Lonza, to produce the active ingredient in both drugs, and that this Lonza GS Expression System infringes on the '688 Patent.

Novartis produces a medication, Lucentis®, that is a competitor of Regeneron's Eylea®. Novartis began to manufacture, market, and sell Lucentis® in 2007, and, according to Novartis, before Eylea® entered the market in 2011, it was the only approved protein-based therapy indicated for the treatment of AMD, RVO, DME, and DR. Regeneron identified Novartis, and specifically Novartis's Lucentis®, as a competitor in its 2014 Securities and Exchange Commission filings.

Seven years ago, in 2011, Novartis made similar allegations of infringement of the '688 Patent against three other biotechnology companies. See Complaint, Novartis Vaccines & Diagnostics, Inc. et al. v. MedImmune LLC et al., No. 11cv00084, 2011 WL 445672 (D.Del. Jan. 26, 2011). That lawsuit was publicized in at least two industry publications. The parties in that dispute stipulated to a dismissal in 2014.

Novartis filed its initial complaint alleging patent infringement and willful patent infringement against Regeneron on March 19, 2018. Regeneron moved to dismiss the willful infringement allegations on June 21, 2018. On July 20, 2018 Novartis filed the FAC, and on August 3, 2018, Regeneron filed this motion to dismiss the willful infringement claims in the FAC.

Discussion

A claim can survive a motion to dismiss if it contains "sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (citation omitted). This is "a standard that asks for more than a sheer possibility that a defendant has acted unlawfully." Montero v. City of Yonkers, 890 F.3d 386, 394 (2d Cir. 2018) (citation omitted). A court "need not accept conclusory allegations or legal conclusions couched as factual allegations." Milan v. Wertheimer, 808 F.3d 961, 963 (2d Cir. 2015) (citation omitted). The

> plausibility standard, which applies to all civil actions, does not prevent a plaintiff from pleading facts alleged upon information and belief where the facts are peculiarly within the possession and control of the defendant, or where the belief is based on factual information that makes the inference of culpability plausible.

Arista Records, LLC v. Doe 3, 604 F.3d 110, 120 (2d Cir. 2010) (citation omitted).

Regeneron moves to dismiss Novartis's claims of willful infringement justifying enhanced damages. Under Section 284 of the Patent Act, a court may increase an award of damages in a patent infringement case by up to three times. 35 U.S.C. § 284. In Halo Elecs., Inc. v. Pulse Elecs., Inc., 136 S. Ct. 1923 (2016), the Supreme Court held that such enhanced damages are

appropriate where a district court finds, in its discretion, the case before it to be an "egregious case[ ] of misconduct beyond typical infringement." Id. at 1935. The Court in Halo abrogated a Federal Circuit test for willful infringement, explaining that "subjective willfulness of a patent infringer, intentional or knowing, may warrant enhanced damages, without regard to whether his infringement was objectively reckless." Id. at 1933. It is the "knowledge of the actor at the time of the challenged conduct" that must be assessed. Id. Accordingly, after Halo, "[k]nowledge of the patent alleged to be willfully infringed continues to be a prerequisite to enhanced damages." WBIP, LLC v. Kohler Co., 829 F.3d 1317, 1341 (Fed. Cir. 2016). But, "the Court's references to 'willful misconduct' do not mean that a court may award enhanced damages simply because the evidence shows that the infringer knew about the patent and nothing more." Halo, 136 S. Ct. at 1936 (Breyer, J., concurring) (emphasis in original). Rather, as described in the Court's Opinion, to merit enhanced damages, a defendant's conduct must be "willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant or -- indeed -- characteristic of a pirate." Id. at 1932.

In order to survive a motion to dismiss a claim of willful misconduct, a complaint must plausibly plead facts sufficient to support an inference that the infringement at issue is

"egregious" in addition to pleading subjective intent. See, e.g., Finjan, Inc. v. Cisco Sys. Inc., No. 17-CV-00072-BLF, 2017 WL 2462423, at *5 (N.D. Cal. June 7, 2017); Jenkins v. LogicMark, LLC, No. 16-CV-751-HEH, 2017 WL 376154, at *5 (E.D. Va. Jan. 25, 2017). But see, e.g., Valinge Innovation AB v. Halstead New England Corp., No. CV 16-1082-LPS-CJB, 2018 WL 2411218, at *9 (D. Del. May 29, 2018).

Novartis has failed to state a claim for willful infringement because it fails to plead either the necessary subjective intent of infringement or egregiousness. Novartis peppers language that mirrors the standard for willful infringement throughout its FAC. Novartis's references to these terms cannot alone state a claim for willful infringement. The FAC's relevant factual allegations boil down to Regeneron's awareness of the existence of the '688 Patent, of Novartis's existence in the marketplace as a competitor, and of the 2011 patent infringement litigation filed by Novartis. These allegations are insufficient to state a claim for willful infringement.

Noticeably absent from the FAC are allegations that Novartis took steps to affirmatively make Regeneron aware of the existence of the '688 Patent or of Regeneron's alleged infringement of the patent. This silence is a serious roadblock

for this claim since almost seven years have passed between the entry of the Regeneron products in the market and the filing of this claim of infringement.

Finally, Novartis asks the Court to grant it leave to replead its allegations of willful misconduct after it has the opportunity to engage in discovery, should such discovery reveal facts sufficient to make this claim. Rule 16, Fed.R.Civ.P., governs the amendment of pleadings after a scheduling order has been issued and states that "[a] schedule may be modified only for good cause and with the judge's consent." Fed.R.Civ.P. 16(b). "[A] district court . . . does not abuse its discretion in denying leave to amend the pleadings where the moving party has failed to establish good cause, as required by Rule 16(b), to amend the pleadings after the deadline set in the scheduling order." Kassner v. 2nd Ave. Delicatessen Inc., 496 F.3d 229, 243 (2d Cir. 2007). "Whether good cause exists turns on the diligence of the moving party." BPP Illinois, LLC v. Royal Bank of Scotland Grp. PLC, 859 F.3d 188, 195 (2d Cir. 2017) (citation omitted).

A scheduling order was issued in this case on June 27, 2018. That order directed Novartis to amend its complaint by July 19, 2018, and warned that "[i]t is unlikely that plaintiffs will have a further opportunity to amend." Novartis filed its

FAC on July 19.[1] Whether Novartis has established good cause to amend its complaint a second time will be answered at the time it brings a motion to amend.

Conclusion

Regeneron's August 3, 2018 motion to dismiss Novartis's claim for willful infringement is granted.

Dated: New York, New York
October 24, 2018

DENISE COTE
United States District Judge

[1] After Regeneron filed its motion to dismiss the FAC's willful infringement claim on August 2, the Court issued a scheduling order for this motion on August 3, in which the Court reminded the plaintiff that the June 27 scheduling order "alerted the plaintiff that it would likely not have another opportunity to amend."