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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

FLUORDX LLC,

Plaintiff,

v.

QUIDEL CORPORATION,

Defendant.

Case No.: 19-CV-1998 JLS (JLB)

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT’S MOTION TO DISMISS

(ECF No. 13)

Presently before the Court is Defendant Quidel Corporation’s Motion to Dismiss (“MTD,” ECF No. 13). Also before the Court are Plaintiff FluorDx LLC’s Response in Opposition to (“Opp’n,” ECF No. 14) and Defendant’s Reply in Support of (“Reply,” ECF No. 15) the Motion. After considering Plaintiff’s Complaint, the Parties’ arguments, and the law, the Court **GRANTS IN PART** and **DENIES IN PART** Defendant’s Motion.

BACKGROUND

Plaintiff FluorDx, LLC is a California limited liability corporation located in Carlsbad, California. Compl. ¶ 3, ECF No. 1. Plaintiff is the owner by assignment of U.S. Patent Number 9,274,056 (the “’056 Patent”), issued on March 1, 2016. Id. ¶ 5. The ’056 Patent describes an “assay method for detecting the presence of an analyte in a sample using a test strip and then analyzing this strip in a reader that uses an LED light source as the UV excitation source.” Id. ¶ 12.

1 Defendant Quidel Corporation is a Delaware corporation licensed to do business in
2 California and headquartered in San Diego, California. *Id.* ¶ 4. Defendant manufactures
3 and sells the Sofia and Sofia 2 immunoassay test systems. See *id.* ¶ 8. The Sofia system,
4 released in 2011, “use[s] lanthanide fluorochrome particles embedded in particles to test
5 for the presence of various analytes. This system or method uses a lateral flow test strip
6 with lanthanide fluorochrome particles to detect the desired analyte and the test strip is then
7 placed into the Sofia reader, which uses an LED light source to excite fluorescent emission
8 and quantify the result.” *Id.* The Sofia 2 system, released in 2018, is an upgrade to the
9 original Sofia system. *Id.*

10 Plaintiff filed its Complaint on October 17, 2019. See generally *id.* Plaintiff alleges
11 Defendant’s Sofia assay systems directly and indirectly infringe Claims 1, 2, 3, 4, 5, 6, 10,
12 11, 12, 14, 17, 18, and 20 of the ’056 patent. *Id.* ¶¶ 26–38. After being served with the
13 Complaint, Defendant filed the Motion now before the Court. See generally *Mot.*

14 **LEGAL STANDARD**

15 A 12(b)(6) motion to dismiss tests the legal sufficiency of the complaint. Fed. R.
16 Civ. P. 12(b)(6); *Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001). The pleading
17 standard requires only “a short and plain statement of the claim showing that the pleader is
18 entitled to relief.” Fed. R. Civ. P. 8(a)(2). To survive a motion to dismiss, however, the
19 claim to relief must be “plausible on its face.” *Bell Atlantic Corp. v. Twombly*, 550 U.S.
20 544, 570 (2007). Although a complaint need not contain “detailed factual allegations,” it
21 must provide more than “‘naked assertions’ devoid of ‘further factual enhancement.’”
22 *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 555–57). Mere
23 “labels and conclusions, and a formulaic recitation of the elements of a cause of action will
24 not do.” *Twombly*, 550 U.S. at 555.

25 When considering a 12(b)(6) motion, the court must accept all material allegations
26 of the complaint and “construe[them] in the light most favorable to the nonmoving party.”
27 *Cahill v. Liberty Mut. Ins. Co.*, 80 F.3d 336, 337–38 (9th Cir. 1996). The court need not
28 assume the truth of “legal conclusions” or “assume that ‘the [plaintiff] can prove facts that

1 [he or she] has not alleged.” *Naigan v. Nana Servs., LLC*, No. 12-cv-2648 BAS (NLS),
2 2015 WL 300368, at *1 (S.D. Cal. Jan. 22, 2015) (alterations in original) (citing *Assoc.*
3 *Gen. Contractors of Cal. v. Cal. State Council of Carpenters*, 459 U.S. 519, 526 (1983)).
4 Dismissal may be based on the absence of a cognizable legal theory, or failure to allege
5 sufficient facts to support a cognizable legal theory. *Balistreri v. Pacifica Police Dept.*,
6 901 F.2d 696, 699 (9th Cir. 1988). Upon dismissal, the district court should grant leave to
7 amend unless “the pleading could not possibly be cured by the allegation of other facts.”
8 *Lopez v. Smith*, 203 F.3d 1122, 1130 (9th Cir. 2000). When considering claims for
9 infringement of a patent, the pleading standards under *Twombly* and *Iqbal* govern.
10 *Footbalance Sys. Inc. v. Zero Gravity Inside, Inc.*, No. 15-CV-1058 JLS (DHB), 2016 WL
11 5786936, at *2–3 (S.D. Cal. Oct. 4, 2016).

12 ANALYSIS

13 Defendant argues that Plaintiff has not plausibly alleged its claims for (1) direct
14 infringement, (2) indirect infringement, or (3) willful infringement. Mot. at 11–17. The
15 Court considers each argument in turn.

16 I. Direct Infringement

17 Plaintiff’s first claim against Defendant is for direct infringement under 35 U.S.C.
18 § 271(a), for “making, using, importing, offering to sell and selling in the United States the
19 Quidel Sofia and Sofia 2 assay systems.” Compl. ¶ 23. To state a claim for direct patent
20 infringement, a plaintiff must allege that the defendant, “without authority[,] makes, uses,
21 offers to sell, or sells any patented invention.” 35 U.S.C. § 271(a); see also *Joy Techs.,*
22 *Inc. v. Flakt, Inc.*, 6 F.3d 770, 773 (Fed. Cir. 1993) (citing *Hewlett-Packard Co. v. Bausch*
23 *& Lomb Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990), cert. denied, 493 U.S. 1076 (1990)).
24 “To prove infringement, the patentee must show that an accused product embodies all
25 limitations of the claim either literally or by the doctrine of equivalents.” *Cephalon, Inc.*
26 *v. Watson Pharms., Inc.*, 707 F.3d 1330, 1340 (Fed. Cir. 2013). “To establish literal
27 infringement, every limitation set forth in a claim must be found in the accused product,
28 exactly.” *Advanced Steel Recovery, LLC v. X-Body Equip., Inc.*, 808 F.3d 1313, 1319 (Fed.

1 Cir. 2015) (citing *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir.
2 1995)). “Under the doctrine of equivalents, ‘a product or process that does not literally
3 infringe upon the express terms of a patent claim may nonetheless be found to infringe if
4 there is “equivalence” between the elements of the accused product or process and the
5 claimed elements of the patented invention.’” *DePuy Spine, Inc. v. Medtronic Sofamor*
6 *Danek, Inc.*, 469 F.3d 1005, 1016 (Fed. Cir. 2006) (citing *Warner–Jenkinson Co. v. Hilton*
7 *Davis Chem. Co.*, 520 U.S. 17, 21 (1997)).

8 Defendant contends Plaintiff fails to show that every limitation in Claim 1 of the
9 ’056 patent can be found in the accused products. Mot. at 11–13. The relevant portion of
10 independent Claim 1 of the ’056 patent claims:

11 1. An assay method for detecting the presence of an analyte in a sample, the
12 method comprising:

13 a) providing a test strip comprising:

14 i) a label pad, said label pad comprising a plurality of particles
15 having a plurality of lanthanide fluorochrome molecules
16 embedded therein, and a binding member or a hapten of the
17 analyte bound to the particle, said binding member capable of
18 binding to the analyte, wherein said lanthanide fluorochrome
molecules are not chelated.

19 ’056 patent, 11:63–12:5. Defendant asserts that Plaintiff cannot show direct infringement
20 of every limitation because Claim 1 requires that the lanthanide fluorochrome molecules
21 are not chelated, *id.* at 7, while the lanthanide fluorochrome molecules in the Sofia systems
22 are chelated. *Id.* at 12.

23 Plaintiff responds, arguing that it pled a plausible claim of infringement supported
24 by sufficient facts. Opp’n at 15–16. Plaintiff contends that whether the lanthanide
25 fluorochrome molecules are chelated “is in reality an issue of claim construction.” *Id.* at
26 16. Plaintiff asserts that construing the term should be done only after the Court allows
27 briefing and holds a hearing, and that claim construction should not be decided on a motion
28 to dismiss. *Id.* at 17 (citing *Fujitsu Ltd. v. Belkin Int’l, Inc.*, 782 F. Supp. 2d 868, 890 (N.D.

1 Cal. 2011) (“Claim construction and infringement analysis should not be resolved on a
2 motion to dismiss.”). And even if the Court does entertain Defendant’s invitation to
3 conduct claim construction at this stage, Plaintiff contends that its construction is supported
4 by both the intrinsic and extrinsic record. *Id.* at 17, 19–21. Plaintiff contends that the
5 inventor acted as his own lexicographer, and that the term “not chelated” in Claim 1 means
6 only that the lanthanide fluorochrome molecules are not chelated to an antibody—it does
7 not mean the lanthanide fluorochrome molecules are not chelated at all. *Id.* at 17.

8 Although “claim construction at the pleading stage may be appropriate” in some
9 limited instances, it “may be inappropriate where . . . the Court finds that it would benefit
10 from additional briefing and evidence presented at the claim construction phase.” *Scripps*
11 *Research Inst. v. Illumina, Inc.*, No. 16-CV-661 JLS (BGS), 2017 WL 1361623, at *4 (S.D.
12 Cal. Apr. 14, 2017). Such is the case here. Plaintiff argues that the inventor acted as his
13 own lexicographer as to the term “not chelated.” *Opp’n* at 20. Plaintiff’s construction is
14 not clearly foreclosed at this stage, and the Court finds that it would benefit from additional
15 briefing and evidence presented. Claim construction at this stage is thus not warranted.

16 Defendant does not contend Plaintiff suffers any other pleading deficiencies as to
17 the claim for direct infringement, and the Court finds Plaintiff’s Complaint sufficiently
18 alleges the required elements. The Court therefore **DENIES** Defendant’s Motion to
19 Dismiss Plaintiff’s direct infringement claim.

20 **II. Indirect Infringement**

21 Plaintiff raises claims of indirect infringement for inducing infringement under 35
22 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c).

23 **A. Inducing Infringement**

24 Plaintiff’s alleges Defendant induced its customers to infringe the ’056 patent by
25 instructing them to use the Sofia assay systems in an infringing manner. *Compl.* ¶ 24. To
26 state a claim for inducement pursuant to 35 U.S.C. § 271(b), “the patentee must show, first
27 that there has been direct infringement, and second that the alleged infringer knowingly
28 induced infringement and possessed specific intent to encourage another’s infringement.”

1 *Kyocera Wireless Corp. v. Int’l Trade Comm’n*, 545 F.3d 1340, 1353–54 (Fed. Cir. 2008)
2 (quoting *Minn. Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1304–05 (Fed. Cir.
3 2002)) (internal quotation marks omitted).

4 Defendant asserts that “Plaintiff’s Complaint alleges no facts showing knowledge
5 and intent that the induced acts constitute patent infringement.” Mot. at 14. Defendant
6 contends that Plaintiff’s allegations regarding intent are insufficient because Plaintiff
7 alleges only that Defendant “provides instructions and teachings to use the Sofia products,”
8 which Defendant contends is insufficient to survive a motion to dismiss. *Id.* (citing *Vita-*
9 *Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1328 (Fed. Cir. 2009)).

10 Plaintiff contends that its allegations of both knowledge and intent are sufficient.
11 Opp’n at 21–25. Regarding knowledge, Plaintiff points to allegations in the Complaint
12 that Defendant was advised of the ’056 patent application in 2009, Compl. ¶ 7; “was
13 advised of the ’056 patent and invited to review and discuss a license” in 2017, *id.* ¶ 9; and
14 responded that it was aware of the ’056 patent in 2018, *id.* ¶¶ 11, 24. As to intent, Plaintiff
15 alleges that Defendant “provided instructions to customers on the use of its products in a
16 manner that directly infringes the ’056 patent.” Opp’n at 24 (citing Compl. ¶¶ 14–19).

17 The Court finds Plaintiff’s allegations “sufficient to plead induced infringement.”
18 See *DermaFocus LLC v. Ulthera, Inc.*, 201 F. Supp. 3d 465, 471 (D. Del. 2016). Drawing
19 all inferences in its favor, Plaintiff has plausibly pled that Defendant had knowledge of the
20 ’056 patent, and that Defendant induced its customers to infringe by providing instructions
21 to operate the Sofia systems using an infringing method. See *id.* (denying motion to dismiss
22 inducement claims where the defendant provided educational materials to customers); see
23 also *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323,
24 1341 (Fed. Cir. 2012) (finding “it is more than reasonable to infer that [the defendant]
25 intended to induce its customers to use its products to practice the patented method” where
26 the defendant advertised its product could be used “to accomplish the[advertised] benefits
27 through utilization of the patented method”).

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1 Defendant’s argument that these allegations are insufficient under Vita-Mix does not
2 change this conclusion. Although the court in Vita-Mix rejected the plaintiff’s arguments
3 that “the product instructions and the design of the device . . . support an inference of
4 intent,” the court rejected those arguments on a motion for summary judgment, finding the
5 “record devoid of actual evidence establishing specific intent to encourage customers to
6 infringe.” 581 F.3d at 1328. At the pleading stage, Plaintiff does not carry the burden to
7 show Defendant had the requisite intent based on evidence in the record; it need only show
8 its allegations are plausible. See *In re Bill of Lading*, 681 F.3d at 1331–32. Because
9 Plaintiff’s allegations of inducement are just that, the Court **DENIES** Defendant’s Motion
10 as to Plaintiff’s induced infringement claim.

11 **B. Contributory Infringement**

12 Plaintiff also alleges that Defendant contributed to infringing the ’056 patent through
13 its sales of the Sofia assay systems. Compl. ¶ 25. To establish contributory infringement
14 under 35 U.S.C. § 271(c), a plaintiff must show: “1) that there is direct infringement, 2)
15 that the accused infringer had knowledge of the patent, 3) that the component has no
16 substantial noninfringing uses, and 4) that the component is a material part of the
17 invention.” *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1326 (Fed. Cir. 2010) (citing 35
18 U.S.C. § 271(c)).

19 Like the inducement claim, Plaintiff contends Defendant lacks sufficient factual
20 allegations to plausibly state a claim for contributory infringement. Mot. at 15–16.
21 Plaintiff argues that Defendant’s allegations “simply mirror the statutory language of
22 Section 271(c) and are insufficient.” *Id.* at 15. Defendant specifically argues that “Plaintiff
23 does not identify . . . which component(s) of Sofia are allegedly known to be especially
24 made or adapted for use in infringing the patent or how that component is not a stable
25 article of commerce suitable for noninfringing use.” *Id.*

26 Also like the inducement claim, the Court finds Plaintiff’s allegations sufficient to
27 plausibly state a claim. As noted above, Plaintiff has sufficiently alleged Defendant’s
28 direct infringement and knowledge of the ’056 patent.

1 As to whether the Sofia systems have noninfringing uses, Plaintiff alleges that
2 Defendant instructs end users to use the Sofia systems in a way that infringes on the '056
3 patent, and that the systems must be used this way because they are "FDA registered[,]
4 meaning the . . . system must be used as directed by [Defendant] for use as a diagnostic
5 test." Compl. ¶ 25. And regarding whether the Sofia systems are a material part of the
6 invention, Plaintiff contends the Sofia systems constitute a "material part of the patented
7 inventions" because they infringe the patent by "automatically perform[ing] the steps of
8 the claim methods of the '056 patent." Id. ¶ 23. Plaintiff plausibly alleges the Sofia
9 systems themselves are an "apparatus . . . for use in practicing a patented process." 35
10 U.S.C. 271(c). Drawing all reasonable inferences in Plaintiff's favor, the Court finds these
11 allegations sufficient. For these reasons, Defendant's Motion to Dismiss Plaintiff's
12 contributory infringement claim is **DENIED**.

13 **III. Willful Infringement**

14 Finally, Plaintiff alleges that Defendant willfully infringed the '056 patent. Compl.
15 ¶ 39. Section 284 of Title 35 of the United States Code allows courts, in their discretion,
16 to "increase the damages up to three times the amount found or assessed" in cases of willful
17 or bad-faith infringement. 35 U.S.C. § 284. "[T]here is 'no precise rule or formula' for
18 awarding damages under section 284." Halo, 136 S. Ct. at 1932 (quoting Octane Fitness,
19 LLC v. ICON Health & Fitness, Inc., 572 U.S. 545, 1756 (2014)). Instead, district courts
20 should narrow their discretion "so that such damages are generally reserved for egregious
21 cases of culpable behavior." Id.

22 "[C]ulpability is generally measured against the knowledge of the actor at the time"
23 the infringement occurs. Id. at 1933. Thus, courts have held that "[k]nowledge of the
24 patent alleged to be willfully infringed" is a "prerequisite to enhanced damages." WBIP,
25 LLC v. Kohler Co., 829 F.3d 1317, 1341 (Fed. Cir. 2016). "[A]llegations of knowledge
26 alone," however, "are insufficient." *Cont'l Circuits LLC v. Intel Corp.*, No. CV16-2026
27 PHX DGC, 2017 WL 2651709, at *8 (D. Ariz. June 19, 2019) (citing Halo, 136 S. Ct. at
28 1936 (Breyer, J., concurring)). While "[s]ection 284 allows district courts to punish the

1 full range of culpable behavior,” Halo, 136 S. Ct. at 1933–34, the “sort of conduct
2 warranting enhanced damages” should be reserved for conduct “variously described . . . as
3 willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or—
4 indeed—characteristic of a pirate.” Id. at 1932. Thus, to plead willful infringement, a
5 plaintiff must generally state facts that show (1) the defendant knew, or should have known,
6 of the patent; and (2) the defendant acted egregiously.

7 Although the Court finds Plaintiff’s Complaint contains sufficient allegations to
8 show knowledge, Plaintiff fails to show egregiousness. “Nothing in the [C]omplaint
9 provides specific factual allegations about [Defendant]’s subjective intent or details about
10 the nature of [Defendant]’s conduct to render a claim of willfulness plausible, and not
11 merely possible.” See *Hypermedia Navigation LLC v. Google LLC*, No. 18-CV-06137-
12 HSG, 2019 WL 1455336, at *4 (N.D. Cal. Apr. 2, 2019). Plaintiff’s only allegations of
13 willfulness are that Defendant “has been involved in license discussions about the ’056
14 patent, yet chose to not take a license,” and that Defendant “either knows or is choosing to
15 willfully blind itself to its infringement of the ’056 patent.” Compl. ¶ 39. Refusing a
16 license alone, however, does not show willfulness; indeed, Defendant’s refusal is “equally
17 consistent with a defendant who subjectively believes the plaintiff’s patent infringement
18 action has no merit.” *Slot Speaker Techs., Inc. v. Apple, Inc.*, No. 13-CV-01161-HSG,
19 2017 WL 4354999, at *2 (N.D. Cal. Sept. 29, 2017). Without more, Plaintiff alleges only
20 “garden-variety” infringement that does not rise to the level of an “egregious case[] of
21 misconduct beyond typical infringement.” Halo, 136 S. Ct. at 1935.

22 The Court therefore **GRANTS** Defendant’s Motion to Dismiss Plaintiff’s willful
23 infringement claim. See *Cont’l Circuits LLC*, 2017 WL 679116, at *11 (dismissing willful
24 infringement claim where plaintiff “alleged sufficient facts to show knowledge, but not to
25 show the additional element of egregiousness”).

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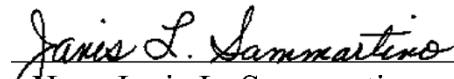
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1 **CONCLUSION**

2 For the reasons stated, the Court **GRANTS IN PART** and **DENIES IN PART**
3 Defendant’s Motion. Specifically, the Court **DENIES** Defendant’s Motion to Dismiss
4 Plaintiff’s direct and indirect infringement claims, **GRANTS** Defendant’s Motion to
5 Dismiss Plaintiff’s willful infringement claim, and **DISMISSES WITHOUT**
6 **PREJUDICE** Plaintiff’s willful infringement claim. Plaintiff **MAY FILE** an amended
7 complaint, if any, by August 18, 2020. If Plaintiff does not file an amended complaint by
8 that date, Defendant **SHALL FILE** a response to the remaining claims in Plaintiff’s
9 Complaint by September 1, 2020.

10 **IT IS SO ORDERED.**

11 Dated: August 4, 2020

12 
13 Hon. Janis L. Sammartino
14 United States District Judge
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