IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

VERINATA HEALTH, INC., *et al.*,

Plaintiffs,

v.

ARIOSA DIAGNOSTICS, INC, *et al.*,

Defendants.
_____/

No. C 12-05501 SI

ORDER GRANTING IN PART MOTION TO DISMISS WITH LEAVE TO AMEND

Defendants Ariosa Diagnostics, Inc. and Laboratory Corporation of America Holdings (LabCorp) have filed a motion to dismiss. The motion is scheduled for hearing on February 22, 2013. Pursuant to Civil Local Rule 7-1(b), the Court finds this matter appropriate for resolution without oral argument, and hereby VACATES the hearing. Having considered the papers submitted, and for good cause shown, the Court hereby GRANTS the motion in part, with leave to amend.

BACKGROUND

This is a patent infringement action initiated by plaintiffs Verinata Health, Inc. and the Board of Trustees of the Leland Stanford Junior University ("Stanford"), against defendants Ariosa and LabCorp. Verinata owns U.S. Patent No. 8,318,430 ("the '430 patent") and is the exclusive licensee of U.S. Patent No. 8,296,076 ("the '076 patent") in the field of genetic analysis by nucleic acid

sequencing.[1] Stanford is the patent owner and licensor for the '076 patent and is joined in the infringement action for this patent because it is a necessary party. Amended Complaint ("AC," Dkt. 22) ¶¶ 3, 4. Verinata and Stanford jointly assert the following claims against the defendants with respect to the '076 patent, and Verinata alone asserts the same claims against the defendants with respect to the '430 patent: (1) direct infringement, (2) induced infringement, and (3) contributory infringement of the asserted patents. Defendants move to dismiss the claims asserted against LabCorp, pursuant to Fed. R. Civ. P. 12(b)(6), arguing that plaintiffs have failed to adequately allege LabCorp's infringement.[2]

Verinata develops non-invasive tests for early identification of fetal chromosomal abnormalities. AC ¶ 11. According to Verinata, in early 2012, Verinata began offering the verifi® prenatal test that analyzes the cellfree DNA from a pregnant woman to determine whether the fetus is at risk of having an abnormal number of chromosomes ("aneuploidy"). *Id.* Verinata alleges that in or around May 2012, Ariosa and LabCorp began offering the Harmony™ Prenatal Test ("Harmony Test"), a non-invasive prenatal test for Down syndrome. *Id.* ¶ 12. Verinata alleges that performance of the Harmony Test infringes the '076 and '430 patents in various ways.

Plaintiffs' allegations regarding LabCorp's involvement rest principally on a May 7, 2012 press release ("Press Release") by Ariosa, cited in the Amended Complaint.[3] Gindler Decl., Ex. 1. Plaintiffs' complaint quotes the Press Release, stating that the Harmony Test "will be *offered through* LabCorp and *will be available* at its 1,000+ patient service centers" (emphasis added). AC ¶ 12.[4] Plaintiffs also rely on technical literature on Ariosa's website describing the Harmony Test to support their infringement allegations (*id.* ¶ 13), and specifically allege that "*Defendants* have [performed] and

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[1] There are three other cases related to this one currently pending in this Court: 1) *Verinata Health, Inc. et al v. Sequenom, Inc., et al.*, Case No. 12-cv-00865-SI; 2) *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, Case No. 11-cv-06391-SI; and 3) *Natera, Inc. v. Sequenom, Inc.*, Case No. 12-cv-00132-SI.

[2] Ariosa and LabCorp also move to dismiss plaintiffs' prayer for enhanced damages. Mot. at 7. In opposition, plaintiffs agree to withdraw their prayer for enhanced damages. The motion, therefore, is GRANTED in that respect.

[3] Both sides agree that the Press Release was incorporated by reference in the Amended Complaint and can be considered on this motion to dismiss.

[4] In their Opposition, plaintiffs also rely on a statement made in the Press Release by LabCorp. that the "Harmony Prenatal Test adds another option to LabCorp's comprehensive prenatal testing menu." Gindler Decl., Ex. 1.

continue to perform the [Harmony Test] on samples of maternal blood." *Id.* ¶ 14 (emphasis added). Plaintiffs assert that both Ariosa and LabCorp "continue to directly infringe the [patents in suit] by practicing one or more claims of the [patents] by, including without limitation, performing the Harmony™ Prenatal Test." *Id.* ¶¶ 20, 28. Plaintiffs further allege that LabCorp separately "continues to encourage Ariosa to perform the [Harmony Test], intending that Ariosa perform the test," thereby inducing infringement, and that LabCorp "has and continues to supply to Ariosa material components . . . having no substantial non-infringing use," thereby contributorily infringing the patents. *Id.* ¶¶ 14-15; *see also id.* ¶¶ 21-22, 29-30.

LEGAL STANDARD

Under Federal Rule of Civil Procedure 12(b)(6), a district court must dismiss a complaint if it fails to state a claim upon which relief can be granted. To survive a Rule 12(b)(6) motion to dismiss, the plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). This "facial plausibility" standard requires the plaintiff to allege facts that add up to "more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). While courts do not require "heightened fact pleading of specifics," a plaintiff must allege facts sufficient to "raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 544, 555.

In deciding whether the plaintiff has stated a claim upon which relief can be granted, the court must assume that the plaintiff's allegations are true and must draw all reasonable inferences in the plaintiff's favor. *See Usher v. City of Los Angeles*, 828 F.2d 556, 561 (9th Cir. 1987). However, the court is not required to accept as true "allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1055 (9th Cir. 2008).

To state a claim of patent infringement, "a plaintiff must allege that the defendant makes, uses, offers to sell, or sells the patented invention within the United States, during the term of the patent, and without authority of the patent holder." *Advanced Cardiovascular Sys., Inc. v. SciMed Life Sys., Inc.*, 989 F. Supp. 1237, 1249 (N.D. Cal. 1997). A claimant is not required to "to set out in detail the facts upon which he bases his claim"; instead, the complaint "need only plead facts sufficient to place the

alleged infringer on notice." *Phonometrics, Inc. v. Hospitality Franchise Sys., Inc.*, 203 F.3d 790, 794 (Fed. Cir. 2000). In this District, Local Patent Rule 3-1 requires detailed disclosure of asserted claims and infringement contentions shortly after the initial Case Management Conference, to provide further information about the scope of the patent infringement claim.

DISCUSSION

1. Direct Infringement

Defendants do not challenge the adequacy of the allegations of direct infringement against Ariosa. *See* Motion to Dismiss ("Mot.," Dkt. 27). Instead, defendants attack the sufficiency of the complaint against LabCorp, arguing that although the FAC alleges that defendants are "practicing" the patent, it fails to allege directly that LabCorp "makes, uses or sells" the patented invention as required by Fed.R.Civ.P. 84, Form 18. Mot. at 4. (citing *In re Bill of Lading Transmission & Processing Systems Patent Litigation*, 681 F.3d 1323, 1331-33 (Fed. Cir. 2012)). Defendants contend – without citation to the Amended Complaint or to judicially noticeable facts – that LabCorp "does nothing more than make the test available to patients and draw blood from patients (which is then supplied to Ariosa, which performs the Harmony Test)." Mot at 4. Defendants also assert that LabCorp cannot be liable for selling or offering to sell the Harmony Test, because in order to be liable for direct patent infringement, one who sells the patented method must also use every step of that method in its entirety. *Id.* at 5 (citing *Lincoln Nat. Life Ins. Co. v. Transamerica Life Ins. Co.*, 609 F.3d 1364, 1370 (Fed. Cir. 2010)).

Regarding the "make" or "use" prongs of § 271(a), plaintiffs contend that their allegations – that defendants are "providing" and making the Harmony Test available through LabCorp, as supported by references to the Press Release – suffice at this juncture. Plaintiffs argue, and the Court agrees, that defendants' unsubstantiated fact-based claims regarding the actual role LabCorp plays with respect to preparing and running the Harmony Test may not be considered on this motion to dismiss. Plaintiffs' Opposition to Motion to Dismiss ("Oppo.," Dkt. 28) at 5-7. However, the Amended Complaint does not expressly allege that LabCorp "makes" or "uses" the Harmony Test. Therefore, the Court GRANTS defendants' motion to dismiss, but allows plaintiffs leave to amend to clearly allege that LabCorp is directly liable under the "make" and "use" prongs of § 271(a). If amended, the revised allegations,

when combined with inferences from language contained in Ariosa's Press Release, would be plausible, non-speculative and sufficient.

Regarding the "sell or offers to sell" prong of 35 U.S.C. § 271(a), plaintiffs respond that by quoting the Press Release language about Ariosa and LabCorp "offering" the Harmony Test and making the test "available" through LabCorp, they have adequately alleged that both defendants directly infringe by selling and offering to sell. Oppo. at 3. In a footnote, plaintiffs acknowledge that their complaint does not directly allege that LabCorp "sells" or "offers to sell" under 35 U.S.C. § 271(a), but argue that the language regarding LabCorp "offering" and making available the test is sufficient given the context and alleged relationship between the parties. Oppo. at 3 & n.3. In any event, plaintiffs request that, "if necessary," leave to amend be given to make this "minor change." *Id.*

The Court finds that there is nothing in plaintiffs' Amended Complaint, or other facts subject to judicial notice, that would make an express allegation that LabCorp sells and/or offers to sell the Harmony Test implausible. Therefore, the Court finds that plaintiffs should be given leave to amend to expressly allege that LabCorp sells and/or offers to sell the Harmony test in violation of § 271(a). As such, defendants' motion to dismiss the direct infringement claim is GRANTED with leave to amend on this narrow ground as well.[5]

2. Contributory Infringement

Defendants argue that plaintiffs failed to explicitly identify a "material component" required to allege contributory infringement under 35 U.S.C. § 271(c). Mot. at 6. Morever, the defendants argue that a maternal blood sample taken by LabCorp cannot be considered a "material component" because it has non-fringing uses, such as other diagnostic tests, which are substantial because they are not

[5] Defendants also contend that allegations regarding the "sell" prong under § 271(a) cannot, standing alone, state a claim for direct infringement of the *method* claims at issue here because method claims may only be infringed by "performing" them. *See* Mot. at 5; Reply at 4-6 (relying on *Lincoln Nat'l Life Ins. Co. v. Transamerica Life Ins.* Co., 609 F.3d 1364, 1370 (Fed. Cir. 2010) ("The law of this circuit is axiomatic that a method claim is directly infringed only if each step of the claimed method is performed."")). Plaintiffs respond that no Federal Circuit case directly supports this proposition and that recent district court cases reject it. Oppo. at 4-5 (distinguishing *Lincoln* as a case relying solely on the "use" prong of § 271(a)). Here, because the Court has found that if plaintiffs amend to directly allege the "use" and "make" prongs, the allegations will be sufficient for purposes of pleading direct infringement, the Court need not reach this argument.

"unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *Id.*, citing *Vita-Mix Corp. v. Basic Holding, Inc*., 581 F.3d 1317, 1327 (Fed. Cir. 2009). Finally, defendants argue that plaintiffs have, in any event, failed to allege specific *facts* indicating that LabCorp supplies components that have no substantial non-infringing uses. *See In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d at 1337 (plaintiff must "plead facts that allow an inference that the components sold or offered for sale have no substantial non-infringing uses.").

Plaintiffs respond that the only product Ariosa has *is* the Harmony Test, thus any maternal blood draw sent from LabCorp to Ariosa will be used only for infringing purposes, and the fact that blood draws are used to run many other diagnostic tests is irrelevant. Oppo. at 8. Although the factual allegations in the Amended Complaint are sparse, given the factual context of the relationship as alleged in the Amended Complaint and supported by reference to the Press Release, the Court finds that plaintiffs have adequately alleged that LabCorp provides blood samples to Ariosa "knowing the same to be especially made" for the allegedly infringing Harmony Test. 35 U.S.C. § 271(c).

3. Induced Infringement

Defendants contend that "mere knowledge of infringement by others is not tantamount to inducement; specific intent and action to induce infringement must also be shown." Reply at 7-8, citing *DSU Medical Corp. v. JMS Co., Ltd.*, 471 F. 3d 1293, 1306 (Fed. Cir. 2006) ("inducement requires evidence of culpable conduct, directed to encouraging another's infringement, not merely that the inducer had knowledge of the direct infringer's activities"). Defendants argue that LabCorp could not have directed Ariosa to infringe because the Harmony Test is proprietary technology known and developed by Ariosa without LabCorp's involvement. Reply at 8.

Plaintiffs counter that to survive a motion to dismiss, the complaint need only state facts "plausibly showing" that LabCorp specifically intended Ariosa to infringe and knew that Ariosa's acts constituted infringement. Oppo. at 9, quoting *In re Bill of Lading*, 681 F.3d at 1339. Moreover, plaintiffs note that "intent may be inferred from stated facts 'in the context in which they occurred and from the standpoint of the speakers and listeners within that context.'" *Id.* (quoting *In re Bill of Lading*, 681 F.3d at 1340); *see also id.* at 1343 ("[W]hat is necessary is that facts, when considered in their

entirety and in context, lead to the common sense conclusion that a patented method is being practiced.").

The Court finds that in context and considering the Press Release, plaintiffs sufficiently plead that LabCorp intended Ariosa to perform the allegedly infringing Harmony Test, LabCorp has knowledge of the manner in which the Harmony Test is allegedly infringing, and LabCorp intends Ariosa to perform the allegedly infringing test on blood draws LabCorp provides to Ariosa.

CONCLUSION

For the foregoing reasons and for good cause shown, the Court hereby GRANTS the motion to dismiss on the direct infringement claim against LabCorp, with leave to amend, and GRANTS the motion to dismiss the prayer for enhanced damages. The Court DENIES the Motion to Dismiss on the contributory and induced infringement claims. The Second Amended Complaint must be filed within ten (10) days of the date of this Order.

IT IS SO ORDERED.

Dated: February 20, 2013

SUSAN ILLSTON
United States District Judge