IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOMÉRIEUX, S.A. and BIOMÉRIEUX, INC.,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	C.A. No. 18-21 (LPS)
	:	
HOLOGIC, INC., GRIFOLS S.A., and GRIFOLS DIAGNOSTIC SOLUTIONS INC.,	:	
	:	
Defendants,	:	
	:	

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MEMORANDUM OPINION

September 25, 2018
Wilmington, Delaware

STARK, U.S. District Judge:

Plaintiffs bioMérieux, S.A., and bioMérieux, Inc.'s (together, "Plaintiffs" or "bioMérieux") assert in their February 2, 2017 Complaint (D.I. 1) ("Complaint" or "Compl.") that Defendants Hologic, Inc. ("Hologic"), Grifols Diagnostic Solutions Inc. ("GDS"), and Grifols, S.A. ("GSA") (together, "Defendants") infringe Plaintiffs' U.S. Patent Nos. 8,697,352 ("the '352 patent") and 9,074,262 ("the '262 patent"). On April 3, 2017, Hologic and GDS filed a motion to dismiss, pursuant to Federal Rule of Civil Procedure 12(b)(6), on the grounds that Plaintiffs "failed to allege sufficient facts to make its claims plausible, leaving required elements of its claims unaddressed." (D.I. 18; D.I. 17) On May 2, 1027, GSA filed its own motion to dismiss, adopting by reference the briefing provided by Hologic and GDS. (D.I. 26; D.I. 27) Then, on January 3, 2018, the parties consented to transfer the case from the Middle District of North Carolina to this Court. (D.I. 56; D.I. 57) Defendants refiled their motion to dismiss. (D.I. 69) Later, the Court ordered and obtained supplemental letter briefs on the effect of the transfer on which Circuit's law to apply. (*See* D.I. 119; D.I. 120)

The Court will deny Defendants' motion.

I. BACKGROUND

The present dispute revolves around alleged infringement of Plaintiffs' patents relating to HIV-1 testing technology. "bioMérieux has developed innovative tests for screening for infectious diseases in the blood and blood products received by transfusion recipients, surgical patients, and clinical trial participants." (Compl. at ¶ 13) The Complaint asserts that Plaintiff discovered an improved means of screening for HIV-1 in the 1990s. (*Id.* at ¶ 14) In particular, the asserted patents responded to the need to test for mutations and strains of HIV-1 that were being missed by other tests. (*Id.* at ¶¶ 23-25) The scientists collaborating on the project "identified nucleotide sequences derived from a particular part of the HIV-1 genome that, when

used in primer sets with a transcription-based amplification technique, were capable of detecting nearly all known HIV-1 subtypes. The resulting methods were much more sensitive than methods disclosed in the prior art, and delivered results much faster." (*Id.* at ¶ 27)

Plaintiffs' inventions are purportedly claimed in the '352 and '262 patents. The '352 patent is entitled, "Nucleic Acid Sequences that Can Be Used as Primers and Probes in the Amplification and Detection of All Subtypes of HIV-1," and was issued on April 15, 2014; it claims priority to a European Patent Application filed August 8, 1997. (*Id.* at ¶ 29) The '262 patent, entitled "Nucleic Acid Sequences that Can Be Used as Primers and Probes in the Amplification and Detection of All Subtypes of HIV-1," claims priority to the same application. (*Id.* at ¶¶ 29-30) Plaintiffs are co-assignees to both patents. (*Id.*)

The Complaint alleges with respect to Defendants' infringement:

> In particular, Defendants have been party to a distribution agreement under which Hologic will manufacture in the United States products used for amplifying and detecting HIV-1. Those products are sold to Grifols, S.A. and Grifols USA and then resold in the United States and the rest of the world, marketed under the names Procleix HIV-1/HCV Assay, Procleix Ultrio Assay, and Procleix Ultrio Plus Assay (the 'Procleix Tests'). Under their contractual arrangement, Hologic ships the Accused Products to customers identified and contracted by Grifols, S.A. and Grifols USA. The Defendants split the net proceeds of those sales.

(*Id.* at ¶ 35) Plaintiffs accuse two sets of products: the Procleix tests and Aptima tests (Aptima HIV-1 RNA Qualitative Assay and Aptima HIV-1 Quant DX Assay), together the "Accused Tests." (*Id.* at ¶ 36)

The Complaint further alleges:

> The manufacture, use, offer for sale, and sale of the Accused Tests in the United States, with accompanying instructions, infringe and/or induce or contribute to infringement of the Asserted Patents because the tests amplify and detect HIV-1 through the use of

> oligonucleotide primers, promoters, methods, and kits, that are covered by the claims of the Asserted Patents.

(*Id.* at ¶ 38) Plaintiffs assert that Defendants infringe one or more of the claims, including at least claim 1 of each of the two patents, and that the infringement is willful. (*Id.* at ¶¶ 41-43) With respect to willfulness, the Complaint alleges "that Hologic has had knowledge of the Asserted Patents through its efforts over the last several years to revoke foreign counterparts of these patents that issued from the European Patent Office" and by GSA and GDS' relationship with Hologic. (*Id.* at ¶ 43) Plaintiffs allege that this infringement is "willful, wanton, malicious, in bad faith, and deliberate." (*Id.* at ¶ 45)

II. LEGAL STANDARDS

Evaluating a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) requires the Court to accept as true all material allegations of the complaint. *See Spruill v. Gillis*, 372 F.3d 218, 223 (3d Cir. 2004). "The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997) (internal quotation marks omitted). Thus, the Court may grant such a motion to dismiss only if, after "accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief." *Maio v. Aetna, Inc.*, 221 F.3d 472, 481-82 (3d Cir. 2000) (internal quotation marks omitted).

A well-pleaded complaint must contain more than mere labels and conclusions. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). A plaintiff must plead facts sufficient to show that a claim has substantive plausibility. *See Johnson v. City of Shelby*, 135 S. Ct. 346, 347 (2014). A complaint may not be dismissed,

however, for imperfect statements of the legal theory supporting the claim asserted. *See id.* at 346.

"To survive a motion to dismiss, a civil plaintiff must allege facts that 'raise a right to relief above the speculative level on the assumption that the allegations in the complaint are true (even if doubtful in fact).'" *Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007) (quoting *Twombly*, 550 U.S. at 555). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. At bottom, "[t]he complaint must state enough facts to raise a reasonable expectation that discovery will reveal evidence of [each] necessary element" of a plaintiff's claim. *Wilkerson v. New Media Tech. Charter Sch. Inc.*, 522 F.3d 315, 321 (3d Cir. 2008) (internal quotation marks omitted).

The Court is not obligated to accept as true "bald assertions," *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (internal quotation marks omitted), "unsupported conclusions and unwarranted inferences," *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997), or allegations that are "self-evidently false," *Nami v. Fauver*, 82 F.3d 63, 69 (3d Cir. 1996).

III. DISCUSSION

Defendants challenge the sufficiency of bioMérieux's allegations regarding direct, indirect, and willful infringement. Defendants argue that bioMérieux's Complaint "falls well short of the pleading requirements under Rule 8 of the Federal Rules of Civil Procedure." (D.I. 18 at 1) As explained below, the Court disagrees.

A. Direct Infringement

In order to "survive a motion to dismiss under Rule 12(b)(6), a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337, 1347 (Fed. Cir. 2018) (internal quotation marks and citation omitted). This does not require that a plaintiff "'prove its case at the pleading stage.'" *Id.* at 1350. Additionally, the "'Federal Rules of Civil Procedure do not require a plaintiff to plead facts establishing that each element of an asserted claim is met.'" *Id.* Instead, the complaint must merely "place the potential infringer . . . on notice of what activity . . . is being accused of infringement." *Id.* (internal quotation marks and citation omitted).

Defendants allege that "the Complaint fails to include sufficient facts about the accused products or methods and why bioMérieux contends that all of the elements of any one claim of the '352 or '262 patent are met." (D.I. 18 at 2) For example, one of the asserted claims is directed to "[a] pair of oligonucleotide primers for the amplification of a target sequence between two primer binding sites located within the LTR region of the HIV-1 genome." (D.I. 1-1 at 17:30–32 (claim 1)) Defendants assert that, "[i]nstead of providing the requisite facts to make each claim for relief plausible, [the Complaint] couches legal conclusions as facts without any supporting details." (D.I. 28 at 9)

In arguing the allegations are insufficient, Defendants cite to *In re Korean Air Lines Disaster of Sept. 1, 1983* ("*In re KAL*"), 829 F.2d 1171, 1174-76 (D.C. Cir. 1987), to suggest that this Court should look to Third Circuit law (transferee court), but may give "close consideration" to Fourth Circuit law (transferor court). (D.I. 119 at 2) Plaintiffs agree with that Third Circuit law controls. (*See* D.I. 120 at 1) (citing Mu*rphy v. F.D.I.C.*, 208 F.3d 959, 964–66 (11th Cir. 2000))

Plaintiffs' defense of their Complaint begins with pointing out that "district courts have disagreed on exactly how *Iqbal* and *Twombly* should apply to infringement claims." (D.I. 30 at 6-7) Plaintiffs argue that "all that Twombly and Iqbal require is a brief description of what the patent at issue does and an allegation that certain named and specifically identified products or product components also do what the patent does." (*Id.* at 7 (citing, for example, *Gracenote, Inc. v. Sorenson Media, Inc.*, 2017 WL 2116173, at *2 (D. Utah May 15, 2017); *see also* D.I. 120 at 2 (citing *DermaFocus LLC v. Ulthera, Inc.*, 201 F. Supp. 3d 465, 470 (D. Del. 2016); *Zimmer Surgical, Inc. v. Stryker Corp.*, 2017 WL 1296026, at *5 (D. Del. Apr. 6, 2017); *United States Gypsum Co. v. New NGC, Inc.*, 2017 WL 2538569, at *3 (D. Del. June 12, 2017)) Plaintiffs point out that the Complaint "identifies the brand names and function of the accused products . . . and describes, on a limitation-by-limitation basis, how the accused products infringe an exemplary claim." (D.I. 30 at 8) Plaintiffs also note, correctly, that as a practical matter they will be serving infringement contentions at an early stage in the proceedings, providing further clarity as to the charges they are asserting against Defendants. (*Id.* at 10-11)[1]

The Court recently found a patent infringement complaint sufficient where:

> Each of the counts in the Complaint[] follow[ed] essentially the same format: reciting the language of a representative claim, alleging that the accused products practice that claim, and providing examples drawn from product documentation, demonstration and informational videos, user manuals, and/or promotional materials demonstrating the alleged use of some aspect of the accused product of the products performing at least some of the requirements of the representative claim.

[1] Plaintiffs add in their supplemental letter that "[i]n accordance with the Scheduling Order, Plaintiffs served on Defendants on August 7, 2018 "an initial claim chart relating each known accused product to the asserted claims each such product allegedly infringes." (D.I. 120 at 3) (citing Scheduling Order (D.I. 88) at ¶ 7(c))

Align Tech., Inc. v. 3Shape A/S, 2018 WL 4275632, at *5 (D. Del. Sept. 7, 2018). Here, too, the Complaint is supported by various publicly-accessible documents, and as a whole provides "fair notice of how it is [Defendants'] accused products are alleged to infringe the asserted patents." *Id.* at *6; *see also Disc Disease Sols. Inc. v. VGH Sols., Inc.*, 888 F.3d 1256, 1260 (Fed. Cir. 2018) (finding sufficient allegations that accused products "meet each and every element of at least one claim" that were supported by identification of accused products as well as photos of products and their packaging).

Plaintiffs' Complaint adequately alleges direct infringement. *See N. Star Innovations, Inc. v. Micron Tech., Inc.*, 2017 WL 5501489, at *1 (D. Del. Nov. 16, 2017) ("Plaintiff needs to have pleaded facts that plausibly indicate that Defendant's accused products practice each of the limitations found in the two asserted claims."). While more is required than a bare recitation of the claim language and an identification of the products, here Plaintiffs have done more.

Notably, as Plaintiffs point out, "the primer sequences used by the Accused Products in this case were a secret at the time of the filing of the Complaint." (D.I. 120 at 2) Plaintiffs cannot be charged with knowing, at the time they drafted their Complaint, non-public information they could only obtain after filing suit and obtaining discovery. It was appropriate for Plaintiffs here to rely on publicly-available information, namely "the published package insert for the Procleix Ultrio Assay" to support their allegations. (*Id.* at 3)

This portion of Defendants' motion will be denied.

B. Indirect Infringement

Indirect infringement includes induced infringement and contributory infringement. *See Courtesy Prods., L.L.C. v. Hamilton Beach Brands, Inc.*, 73 F. Supp. 3d 435, 440 (D. Del. 2014) (citing 35 U.S.C. § 271(b) & (c)). Under § 271(b), "whoever actively induces infringement of a

patent shall be liable as an infringer." To prove induced infringement, the patentee "'must show direct infringement, and that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement.'" *Princeton Dig. Image Corp. v. Ubisoft Entm't SA*, 2016 WL 6594076, at *3 (D. Del. Nov. 4, 2016) (quoting *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1363 (Fed. Cir. 2012)) Contributory infringement under § 271(c) requires a patentee to demonstrate that the alleged infringer "has sold, offered to sell or imported into the United States 'a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process . . . knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use.'" *Id.*

To state a plausible claim for induced or contributory infringement, the plaintiff "must, *inter alia*, sufficiently allege some underlying act of direct infringement." *Varian Med. Sys., Inc. v. Elekta AB*, 2016 WL 3748772, at *3 (D. Del. July 12, 2016) (citing *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2117 & n.3 (2014)). Additionally, for both types of indirect infringement, the plaintiff must "allege facts allowing the reasonable inference that the defendant had knowledge of the patent-in-suit in the key time period, and that its products infringed that patent." *Princeton Dig. Image Corp.*, 2016 WL 6594076, at *4.

1. Induced Infringement

Defendants allege that "bioMérieux has failed to plead sufficient factual allegations that render Defendants' knowledge of the patents or Defendants' knowledge of potential infringement plausible." (D.I. 18 at 2) In particular, Defendants argue that "[n]o facts support an inference that Hologic knew its customers were infringing the asserted patents." (*Id.* at 13) In response, Plaintiffs argue that "[Defendants] have waged an unsuccessful, years-long

campaign before the European Patent Office urging authorities to revoke the European counterparts to the two U.S. patents-in-suit." (D.I. 30 at 14) (citing Compl. at ¶¶ 28, 43) In the context of the Complaint filed here, "bioMérieux does not rely on 'the mere fact of publication' to establish knowledge; it alleges actual knowledge, demonstrated by Defendants' own actions," which is adequate. (D.I. 30 at 14 n.10) The sufficiency and plausibility of Plaintiffs' allegations of Defendant's knowledge is further supported by the allegation that "the parties compete within a small industry and [] the invention has achieved some notoriety." (*Id.* at 15) (citing *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1342 (Fed. Cir. 2016))

The Court further agrees with Plaintiff that the business relationship alleged in the Complaint among Hologic, GDS, and GSA, is sufficient at the pleading stage to render plausible the allegation that all three entities had the requisite knowledge. (*Id.* at 14 n.11) This business relationship relates directly to the accused products. (*Id.*) (citing Compl. at ¶ 35)

Further, the allegations that Defendants advertise the use of the accused product supports an inference of knowledge and intent. (*See* D.I. 30 at 16-17) (citing *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1341-42 (Fed. Cir. 2012); *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010)) By alleging sales and marketing, and by pointing to the product labeling that would induce infringement if followed, the Complaint sufficiently alleges knowledge and intent to induce infringement.

2. Contributory Infringement

Plaintiffs assert that they meet the requirements of pleading contributory infringement by pleading that the "[a]ccused products have no substantial non-infringing uses and are not a staple article of commerce." (Compl. ¶¶ 52, 59) Defendants contend that Plaintiffs must allege specific facts that go toward the allegation of no non-infringing uses. (*See* D.I. 18 at 16) (citing

Intellectual Ventures I LLC v. Bank of Am., Corp., 2014 WL 868713, at *2 (W.D.N.C. Mar. 5, 2014)) The Court agrees with Plaintiffs that they have "plead, with clarity, [] that the accused products cannot test blood samples without the incorporated, patented technology screening also for the presence of HIV-1." (D.I. 30 at 18) This pleading is sufficient to withstand the motion to dismiss.

C. Willful Infringement

In *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923, 1926 (2016), the Supreme Court abrogated the Federal Circuit's "objective recklessness" standard for willful infringement, adding that "[a] patent infringer's subjective willfulness, whether intentional or knowing, may warrant enhanced damages." The Court also explained that enhanced damages under 35 U.S.C. § 284 "should generally be reserved for egregious cases typified by willful misconduct." *Id.* at 1934.

Notwithstanding Defendants' contention (*see* D.I. 18 at 2), the Court finds sufficient plausibility in Plaintiffs' willfulness allegations. Allegations of egregiousness are not required at the pleading stage. *Align Tech.*, 2018 WL 4275632, at *8. Accordingly, this portion of the motion will be denied.

IV. CONCLUSION

For the foregoing reasons, the Court will deny Defendants' motion to dismiss. An appropriate Order follows.