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THE REGENTS OF THE UNIVERSITY OF CALIFORNIA.

Plaintiff,

VS.

BOSTON SCIENTIFIC CORPORATION,

Defendant.

CASE No. 16-cv-06266-YGR

ORDER DENYING MOTION TO DISMISS

Re: Dkt. No. 32

Plaintiff The Regents of the University of California ("the Regents") brings this patent infringement action against Defendant Boston Scientific Corporation ("BSC") alleging claims for contributory infringement and actively inducing infringement of two patents, United States Patent No. 6,164,283 ("the '283 Patent"), entitled "Device And Method For Forming A Circumferential Block In A Pulmonary Vein;" and United States Patent No. 6,502,576 ("the '576 Patent"), entitled "Device And Method For Forming A Circumferential Block In A Pulmonary Vein." (Dkt. No. 1, Complaint.) The patents describe a method used by physicians to treat irregular heart rhythms known as atrial fibrillation ("AFib"), and the Regents assert that the patented methods are now the "universally-adopted procedure" for treating AFib ("the Patented Method"). (Complaint ¶ 37.) The Regents allege that BSC has infringed on the patents by actively inducing and contributing to physicians' direct infringement of practicing the Patented Method. BSC has filed a motion to dismiss the complaint on the grounds of failure to state a claim.

Having carefully considered the papers submitted and the pleadings in this action, and for the reasons set forth below, the Court **DENIES** the Motion to Dismiss.

T. APPLICABLE STANDARD

To survive a motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (citation omitted); see also Fed. R. Civ. P. 12(b)(6). "A pleading that offers 'labels and

conclusions' or a 'formulaic recitation of the elements of a cause of action will not do.' Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Iqbal*, 556 U.S. at 678 (citation omitted). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements" will not suffice. *Id.* at 679.

In general, the Court "may not consider any material beyond the pleadings in ruling on a Rule 12(b)(6) motion." *United States v. Corinthian Colleges*, 655 F.3d 984, 998 (9th Cir. 2011) (quotations omitted). However, the Court may consider materials attached to the complaint and documents properly the subject of judicial notice. *Id.* at 999; *see also Davis v. HSBC Bank Nevada*, *N.A.*, 691 F.3d 1152, 1160 (9th Cir. 2012).

II. DISCUSSION

BSC argues that the complaint alleges physicians directly infringe using a wide range of medical devices and related equipment, sold by BSC and others. The complaint lists an array of BSC devices, including various products falling into the categories of ablation catheters, diagnostic catheters, access catheters, mapping catheters, and ablation generators. (Complaint ¶ 46.) BSC contends that many of these devices do not perform any step of the claimed Patented Method, and that others are not FDA-approved for such treatment and therefore not promoted by BSC for those uses. Thus, BSC contends, the complaint's allegations of contributing to or actively inducing physicians' use of their devices to perform the patented method are not plausible.

A. Contributory Infringement

"Contributory infringement occurs if a party sells or offers to sell, a material or apparatus for use in practicing a patented process, and that 'material or apparatus' is material to practicing the invention, has no substantial non-infringing uses, and is known by the party 'to be especially made or especially adapted for use in an infringement of such patent." *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1337 (Fed. Cir. 2012) (citing 35 U.S.C. § 271(c)). A product, or component of a product, that is "specially adapted for use in the patented process and with no substantial non-infringing use, would plainly be 'good for nothing else' but infringement," making its seller liable. *Ricoh Co. v. Quanta Computer, Inc.*, 550 F.3d 1325, 1337 (Fed. Cir. 2008) (quoting *Metro-Goldwyn-Mayer Studios Inc. v. Grokster*, 545 U.S.

913, 932 (2005)). A substantial non-infringing use is one that is not unusual, occasional, or aberrant. *In re Bill of Lading*, 681 F.3d at 1337 (citing *Vita–Mix Corp. v. Basic Holdings, Inc.*, 581 F.3d 1317, 1327–29 (Fed.Cir.2009)).

Here, the Regents allege that BSC contributed to direct infringement by third-party physicians through its purposeful design, manufacture, and promotion of two particular devices physicians use only in performing the Patented Method: (1) "looped" mapping catheters; and (2) certain catheter "sheaths." (Complaint ¶ 47.) A complaint may be based upon "indirect infringement premised on circumstantial evidence of direct infringement by unknown parties." *In re Bill of Lading*, 681 F.3d at 1336. "[A] plaintiff need not identify a *specific* direct infringer if it pleads facts sufficient to allow an inference that at least one direct infringer exists." *Id.* (emphasis in original). "[W]here an alleged infringer designs a product for use in an infringing way and instructs users to use the product[s] in an infringing way, there is sufficient evidence for a jury to find direct infringement" as a predicate to an indirect infringement claim. *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1385, 1365 (Fed. Cir. 2012).

Here, the Complaint alleges in sufficient detail that these mapping catheters and sheaths, including the particular model names identified in each category, are essential to and part of the system of hardware that enables performance of the Patented Method. (Complaint ¶¶ 27, 31, 43, 46–48.) To the extent BSC seeks greater specificity and detail, it may do so in discovery. Further, the Complaint sufficiently alleges that these mapping catheters and sheaths have no substantial non-infringing uses.

Contrary to BSC's contention, the Court cannot determine from the face of the Complaint and its exhibits that there are substantial non-infringing uses for these mapping catheters and sheaths. While the documents attached to the complaint discuss certain BSC products and their functions, the Court cannot determine from these documents that the alleged mapping catheters and sheaths carry out functions constituting substantial non-infringing uses. This is, at best, a matter to be established with an evidentiary record at summary judgment.

B. Actively Induced Infringement

To allege a claim of induced infringement, the Complaint must set forth facts to show that BSC specifically intended physicians' direct infringement (*i.e.*, practice of the Patented Method)

and knew that the physicians' conduct would infringe on the patents. *In re Bill of Lading*, 681 F.3d at 1339. Specific intent to induce infringement may be established through circumstantial evidence and inferred from the circumstances. *Id.* at 1340; *see also Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936 (2005) ("advertising an infringing use or instructing how to engage in an infringing use, show an affirmative intent that the product be used to infringe"); *Metabolite Laboratories, Inc., v. Laboratory Corp.*, 370 F.3d 1354, 1365 (Fed. Cir. 2004) (affirming judgment where jury could find intent to induce infringement based upon evidence defendant's "own publications . . . specifically directed to the medical doctors" who ordered defendant's products).

As set forth above, the direct infringement by physicians practicing the Patented Method has been alleged sufficiently. (Complaint at ¶¶ 43, 46-48, 73, 86.) The Regents identify several categories of BSC devices used in performing the Patented Method, and identify specific BSC product model names within those categories. (*Id.* at ¶ 46.) To the extent more specific identification of the BSC products is necessary, it will be accomplished by the required disclosures under the Patent Local Rules.

With respect to the acts of induced infringement and BSC's intent, the Complaint alleges that BSC marketed, promoted, and sold their devices to doctors to be used for performing the Patented Method, and trained doctors to perform the Patented Method (using BSC products), establishing that BSC was aware of and intended doctors to perform the Patented Method using those devices. (*Id.* at ¶¶ 43, 45, 46, 47, 48.) The Complaint alleges seminars, tradeshows, marketing materials, and training programs used by BSC to promote the use of BSC devices to practice the Patented Method. (*Id.* at ¶¶ 50-66.) These allegations are sufficient to allege the basis for the claim of induced infringement of the alleged patents, and that BSC's conduct was intentional and done with knowledge that it was promoting direct infringement by the doctors.

Contrary to BSC's contentions, it does not "defy common sense" to infer that BSC actively promotes the sale of its products for use in carrying out the Patented Method, even if that use would be outside the product's approved FDA use, particularly where the pleadings plausibly allege their promotion for such use. *See Andrulis Pharm. Corp. v. Celgene Corp.*, No. CV 13-1644-RGA, 2014 WL 1572906, at *2 (D. Del. Apr. 10, 2014) ("[j]ust because the FDA labels

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materials as 'non-promotional' does not mean that doctors do not view these materials as promoting off-label uses"); *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1340 (Fed.Cir.2012) ("a court must assess the facts in the context in which they occurred and from the standpoint of the speakers and listeners within that context."). To the extent that BSC asserts that some of its products are incapable of being used to perform the Patented Method as alleged, the truth of such assertion is not apparent from the face of the Complaint. Indeed, much of BSC's argument relies on matters outside the pleadings and more properly suited for a determination based upon a factual record.

Accordingly, the Motion to Dismiss is **DENIED**.

This terminates Docket No. 32.

IT IS SO ORDERED.

Dated: May 30, 2017

YVONNE GONZALEZ ROGERS
UNITED STATES DISTRICT COURT JUDGE

Juan Gyaloflee