United States District Court
Northern District of California

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

INNOVATIVE HEALTH SOLUTIONS, INC., Plaintiff, v. DYANSYS, INC., et al., Defendants.	Case No. 14-cv-05207-SI **ORDER GRANTING IN PART DEFENDANTS' MOTION TO DISMISS SECOND AMENDED COMPLAINT AND GRANTING LEAVE TO AMEND** Re: Dkt. No. 101

On May 15, 2015, the Court held a hearing on defendants' motion to dismiss the second amended complaint. For the reasons set forth below, the Court GRANTS defendants' motion in part, and GRANTS plaintiff leave to amend.

BACKGROUND

This case was originally filed on September 12, 2014, in the United States District Court for the Middle District of Florida. On September 30, 2014, plaintiff filed a first amended complaint. By order filed November 25, 2014, this case was transferred into this district. On February 12, 2015, the Court granted the parties' stipulation permitting plaintiff leave to file a second amended complaint ("SAC"). Now before the court is defendants' motion to dismiss the SAC.

Plaintiff IHS, is an Indiana corporation engaged in the business of marketing, selling, and distributing a medical device called P-STIM throughout Florida and the United States. SAC ¶ 4. The SAC alleges that defendant DyAnsys, Inc. is a California corporation "engaged in a business that competes with IHS and which . . . has passed itself off as the source of PSTIM, and has deliberately endangered and continues to endanger patients throughout the United States by

distributing and selling an Indian-made medical device that is not approved by, and has never been approved by, the FDA and for which the FDA has issued an import alert preventing its importation into the United States." *Id.* ¶ 5. Defendant Srini Nageshwar is the CEO of DyAnsys and "is the moving force behind the infringing, tortious, and dangerous misconduct committed by DyAnsys." *Id.* ¶ 6. The SAC alleges that defendant Products for Doctors, Inc. (sometimes "PD"), is a California corporation believed to be an agent or representative of DyAnsys, and that defendant James Bradford "holds himself out as an Executive Partner of Products for Doctors, Inc. and is believed to be the moving force behind the infringing, tortious, and dangerous misconduct of Products for Doctors, Inc." *Id.* ¶¶ 7-8.

According to the SAC, "[s]ince at least as early as 2010, IHS, itself and by and through its predecessor in interest, has been continuously using P-STIM as a trademark to identify a medical device for administering autonomic nervous system and vascular stimulation (hereinafter referred to as the 'PSTIM medical device')." *Id.* ¶ 9. The SAC alleges that "P-STIM is a mark owned internationally by Biegler GbmH, a company in Austria that manufactures the P-STIM medical device for IHS and licenses the mark to IHS for use in the United States." *Id.*[1]

IHS, in conjunction with Biegler, originally began selling its P-STIM medical device under FDA 510(K) Clearance No. K050123. *Id.* ¶ 11. The SAC alleges that "[a]s a result of IHS' tremendous promotional, marketing and sales efforts, outstanding customer service, exponential sales growth, and the exceptionally high quality of its FDA-approved device, P-STIM has acquired a secondary meaning among doctors, patients and the consuming public such that they

[1] According to defendants, Biegler does not possess any registered trademark rights to the "P-STIM" term. Defendants state that "Biegler previously attempted to register the 'P-STIM' mark with the United States Patent and Trademark Office (USPTO), but was unsuccessful in its application. Among other things, the USPTO determined that the mark was 'confusingly similar' to a previously registered 'PC-STIM' mark. Consequently, Biegler possesses, at best, common law rights to the 'P-STIM' mark." Dkt. 101 at 2:18-23. Defendants also state that they "understand that there has been collateral litigation pertaining to Biegler's alleged ownership of the P-STIM Mark and rights to use the technology." *Id.* at 2 n. 1.

In opposition to defendants' motion to dismiss the SAC, plaintiff has submitted the Declaration of Ingeborg Biegler, the President of Biegler GmbH, dated November 10, 2014. The Biegler declaration states that "[w]e have applied for a trademark registration in the United States, but that application is currently pending. It is my understanding based on information I received from my attorneys that the only reason that our application has not yet been granted is that the U.S. trademark office believes that P-STIM is too similar to a previously existing trademark registration for PC-STIM." Acharya Decl. Ex. A ¶ 6.

identify P-STIM as the source of IHS' high quality autonomic nervous system and vascular stimulation medical device." *Id.* ¶ 14.

The SAC alleges that the DyAnsys defendants are previous distributors of the P-STIM medical device manufactured by Biegler, but their distribution rights were terminated by Biegler in July 2013. *Id.* ¶ 16. On or after August 1, 2013, the DyAnsys defendants began importing from India a device almost identical in appearance to that of the P-STIM, which defendants called "P-Stim" and, later, "AnsiStim." *Id.* ¶ 17. The SAC alleges that the DyAnsys defendants then recruited, among others, Products for Doctors as their agents and representatives to market and sell the knockoff 'P-Stim' medical devices on their behalf. *Id.* ¶ 18. The SAC also alleges that defendant Products for Doctors is using an unauthorized reproduction of the "P-STIM stylized font and logo" on their website. *Id.* The SAC alleges that "[a]t the time that they entered the market, Defendants were entirely aware that IHS had been using P-STIM as a trademark, and their actions to date prove what appears to be a willful and deliberate ploy to misappropriate the mark for themselves and to use it to sell flimsy, Indian-made knockoff 'P-Stim' devices." *Id.* ¶ 19.

The SAC alleges that defendants do not have FDA clearance to sell the "knockoff" "P-Stim" devices, and that defendants have misrepresented to the public that their product was cleared under the same FDA 510(K) number assigned to IHS's P-STIM medical device. *Id.* ¶ 20. The SAC also alleges that the "DyAnsys and PD Defendants misrepresented on their respective websites that their Knockoff Device was approved by the FDA, and they otherwise misbranded their product in violation of federal regulations." *Id.* ¶ 22.

On January 2, 2015, while this case was pending, the FDA published Import Alert 89-08, which, according to the SAC, "effectively prohibit[ed] the importation of Defendants' device, whether designated 'P-Stim' or 'AnsiStim' because, contrary to Defendants' misrepresentations to the public, their device does not have and has never had an FDA 510(K) clearance number." *Id.* ¶ 23. The SAC alleges that "[d]espite the Import Alert, PD Defendants continue to represent, as of today, that its 'PStim' device is 'FDA cleared.'" *Id.* ¶ 26, Ex. D. The SAC alleges that "defendants' sales representatives used, and may still be using, an official FDA document – FDA's Summary of Safety and Effectiveness ('SSE') for the FDA 510(K) number assigned to the P-STIM medical device – as a marketing tool to confuse, deceive and steal away IHS' customers." *Id.* ¶ 28.

The SAC alleges that the DyAnsys defendants "also illegally import their 'P-Stim' product by making false statements to the government." *Id.* ¶ 29. "Before an electro-acupuncture medical device is allowed entry into the United States, the importer must provide the FDA and the Customs and Border Patrol with the medical device's 510(K) clearance showing that it can be lawfully marketed in the United States. Thus, not only does DyAnsys Defendants' fraud allow them to import ineffective and unsafe products in violation of the federal Food, Drug, and Cosmetic Act, it also violates the federal False Statements Accountability Act of 1996." *Id.*

The SAC alleges that "[b]ecause Defendants wrongfully and misleadingly referenced and relied on the P-STIM FDA 510(K) number, Biegler was forced to obtain a different number for the P-STIM medical device, namely FDA 510(K) 140788, in an effort to allay confusion in the U.S. between IHS' P-STIM medical device and Defendants' Knockoff Device sold under the Counterfeit Designation." *Id.* ¶ 31. Plaintiff alleges that defendants' knockoff device is "flimsy, unreliable, and cheap, it has an extraordinarily high failure rate, routinely malfunctions and breaks down altogether." *Id.* ¶ 33. "Because doctors and patients identify P-STIM with IHS and are unaware that Defendants were, and still may be, selling inferior Knockoff Devices under the Counterfeit Designation, they attribute their negative experiences to IHS, which severely damaged IHS' reputation and goodwill, and to that of the valuable P-STIM trademark." *Id.*

The SAC also alleges that defendants "crafted a scheme predicated on outright falsities in order to drive IHS and the P-STIM mark out of the medical device market altogether." *Id.* ¶ 38. In May 2014, the DyAnsys defendants appeared before the Centers for Medicare and Medicaid Systems ("CMS") and "falsely claim[ed] standing as the 'manufacturer' and seller of the P-STIM medical device." *Id.* ¶ 39. Defendants argued to CMS that "the billing codes for P-STIM are unclear or ambiguous, and that they need to be revised or clarified." *Id.* The SAC alleges that "DyAnsys Defendants were not at all interested in seeking revision or clarification of the codes. Rather, Defendants knew full well that by arguing to CMS that the codes were unclear or ambiguous, this would cause reimbursement concerns within CMS and, based on those concerns alone, CMS would compromise the current Medicare reimbursement status of the product. As a result, CMS decided that no national program operating need was identified for Medicare, Medicaid, and for the private insurance sector." *Id.* ¶ 40. Plaintiff alleges that "[t]his CMS action,

caused by DyAnsys Defendants, caused great harm to covered patients and effectively drove IHS out of the P-STIM business." *Id.* ¶ 41.

The SAC alleges that "[i]n furtherance of their ploy, Defendants created a new designation, ANSiStim, for their Indian-made knockoff medical device, and applied for their own FDA 510(K) clearance number in connection with that device." *Id.* ¶ 42. "Knowing full well that their Counterfeit Designation and cheap Knockoff Device had already created tremendous confusion in the marketplace and that their misrepresentations to CMS would cause Medicare and Medicaid patients and IHS reimbursement harm, DyAnsys Defendants deliberately set out to denigrate the P-STIM trademark, drive IHS out of business, and then steal all of that business under a newly assumed name, ANSiStim, and a newly assigned 510(K) number." *Id.* ¶ 43. The SAC alleges that "ANSiStim is, in effect, the 'fruit of the poisonous tree.'" *Id.* ¶ 45.

The SAC alleges that "Biegler has delegated to IHS: a) all rights to protect the P-STIM trademark against challenges, including to the Mark's validity and enforceability, being made by Defendants in this case; b) all rights to pursue legal action in connection with statements and actions by DyAnsys to CMS concerning P-STIM." *Id.* ¶ 52. Biegler GmbH also "stipulates and agrees to be bound by any legal determinations made by this Court with respect to the validity and enforceability of the P-STIM mark in the United States." *Id.* ¶ 53. Finally, Biegler GmbH "stipulates and agrees not to pursue any legal action against Defendants seeking damages or injunctive relief resulting from their use, misuse, or infringement of the P-STIM mark or for any of the other claims asserted or that could have been asserted by IHS in this case." *Id.* ¶ 54.[2]

The SAC alleges the following claims: (1) False Designation of Origin and False Descriptions under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a); (2) False Advertising under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a); (3) False Advertising under Cal. Bus. & Prof. Code § 17500; (4) Unlawful Business Practice under Cal. Bus. & Prof. Code § 17200; (5) Unlawful Business Practice under Cal. Bus. & Prof. Code § 17200; (6) Fraudulent Business Practice under Cal. Bus. & Prof. Code § 17200; (7) Unfair, Deceptive, Untrue, or Misleading Advertising under Cal. Bus. & Prof. Code § 17200; (8) Unfair Methods of

[2] Ms. Biegler's declaration reiterates the stipulations alleged in the SAC. Acharya Decl. Ex. A ¶¶ 19-22.

Competition and Unfair or Deceptive Acts or Practices Unlawful Business Practice under Cal. Bus. & Prof. Code § 1770; and (9) trade libel. The SAC seeks damages, restitution and injunctive relief, including enjoining defendants from representing that their products are covered or approved under FDA 510(K) No. K050123, K140788 or any other FDA 510(K) number associated with IHS' P-STIM medical device. *Id*. Prayer for Relief ¶¶ C, E, F. The SAC also seeks an injunction prohibiting defendants from advertising, marketing, distributing or selling their knockoff devices or any equivalent medical device, whether under the name ANSiStim or otherwise. *Id*. ¶ G.

DISCUSSION

The DyAnsys defendants have moved to dismiss the second amended complaint. DyAnsys contends that: (i) Biegler and any other licensees must be joined as parties because IHS alone cannot bring its claims under the Lanham Act, since IHS is neither the owner of the trademark nor an exclusive licensee; (ii) IHS lacks standing to assert claims based upon the Ansys Defendants' alleged misrepresentations to the FDA, since there is no private action for an alleged violation of an FDA regulation; (iii) IHS lacks standing to assert claims based upon the DyAnsys Defendants' alleged misrepresentations to the Centers for Medicare and Medicaid Services ("CMS") since the filing of a CMS application is a constitutionally protected activity; and (iv) all claims against defendant Srini Nageshwar should be dismissed because, as president of DyAnsys, he cannot be held personally liable for the alleged misconduct of the corporation. Defendants Products for Doctors and James Bradford have joined in this motion.

I. Joinder

Defendants move to dismiss plaintiff's Lanham Act claims on the ground that IHS cannot bring its claims on its own, because Biegler, which owns the trademark, and other licensees are necessary parties. Although defendants frame the issue as one of standing, it does not appear that defendants actually contend that IHS lacks standing to bring its Lanham Act claims. Rather, defendants contend that a licensee must generally join the trademark owner as a party in order to

assert a Section 43(a) claim.[3] Defendants also note that IHS is just one of at least two licensees. Defendants argue that Biegler and the other non-exclusive licensees are affected by the outcome of this lawsuit, yet they are not participating in this action.

Defendants contend that this lawsuit could have significant consequences for Biegler, for defendants, and for any other parties who claim an ownership interest in or rights to the disputed mark. The DyAnsys defendants assert that they will be challenging the validity of the trademark, and if they are successful, "it would substantially affect Biegler's common law rights to the mark, as the Court's ruling would have a persuasive (and perhaps preclusive) impact on any subsequent action in which Biegler attempts to enforce the mark against other distributors of p-stim products." Dkt. 101 at 7:5-8. Defendants also argue that if Biegler and its licensees are not named as parties to the action, defendants will face the risk of multiple, duplicative, and potentially inconsistent judgments if these parties ever attempt to separately enforce the mark.

Federal Rule of Civil Procedure 19(a) provides the standard for determining if a party must by joined as "necessary":

> A person who is subject to service of process and whose joinder will not deprive the court of jurisdiction over the subject matter of the action shall be joined as a party in the action if (1) in the person's absence complete relief cannot be accorded among those already parties, or (2) the person claims an interest relating to the subject of the action and is so situated that the disposition of the action in the person's absence may (i) as a practical matter impair or impede the person's ability to protect that interest or (ii) leave any of the persons already parties subject to a substantial risk of incurring double, multiple, or otherwise inconsistent obligations by reason of the claimed interest.

Fed. R. Civ. P. 19(a).

The determination of whether a non-party should be joined pursuant to Rule 19(a) rests within the discretion of the court based on a consideration of the facts of the case and the policies underlying the rule. *See Bakia v. County of Los Angeles*, 687 F.2d 299, 301 (9th Cir. 1982). The Ninth Circuit has instructed courts to consider the following when deciding whether a non-party should be joined:

> Underlying policies include plaintiff's right to decide whom he shall

[3] Defendants note that plaintiff did not attach a copy of the license agreement to the SAC, and thus the terms of plaintiff's license are not before the Court.

> sue, avoiding multiple litigation, providing the parties with complete and effective relief in a single action, protecting the absentee, and fairness to the other party. The determination is heavily influenced by the facts and circumstances of each case. It is a misapplication of Rule 19(a) to add parties who are neither necessary nor indispensable, who are not essential for just adjudication and who have a separate cause of action entirely.

Id.

Where joinder is "necessary" pursuant to Rule 19(a)(1)-(2), but such joinder is not feasible because it would destroy the court's jurisdiction, then the court must determine whether the party is "indispensable," as defined by Rule 19(b). If the party is "indispensable," then the action must be dismissed. Rule 19(b) states:

> Determination by Court Whenever Joinder Not Feasible. If a person as described in subdivision (a)(1)-(2) hereof cannot be made a party, the court shall determine whether in equity and good conscience the action should proceed among the parties before it, or should be dismissed, the absent person being thus regarded as indispensable. The factors to be considered by the court include: first, to what extent a judgment rendered in the person's absence might be prejudicial to the person or those already parties; second, the extent to which, by protective provisions in the judgment, by the shaping of relief, or other measures, the prejudice can be lessened or avoided; third, whether a judgment rendered in the person's absence will be adequate; fourth, whether the plaintiff will have an adequate remedy if the action is dismissed for nonjoinder.

Fed. R. Civ. P. 19(b). Defendants bear the burden of persuasion in arguing for dismissal under Rule 19. *See Clinton v. Babbit*, 180 F.3d 1081, 1088 (9th Cir. 1999).

Plaintiff argues that defendants do not face the risk of multiple, duplicative, and potentially inconsistent judgments because Biegler GbmH has: (a) assigned all rights to protect the P-STIM trademark to IHS (*see* Acharya Decl., Exh. A ¶ 19); (b) agreed to be bound by any and all legal determinations made by this Court with respect to the validity and enforceability of the P-STIM mark in the United States (*id*. ¶ 20); and (c) stipulated and agreed that it will not pursue any legal action against defendants resulting from their use, misuse or infringement of the P-STIM trademark or for any of the other claims asserted or that could have been asserted by IHS in this case. (*id*. ¶ 21.). In addition, plaintiff has filed the declaration of Ms. Biegler, which reiterates the stipulations alleged in the SAC. Acharya Decl. Ex. A ¶¶ 19-22. At the hearing, plaintiff's counsel stated that he had been in contact with Ms. Biegler and that Biegler did not want to participate as a plaintiff in this lawsuit, and counsel confirmed that Biegler agreed to be bound by all of this

Court's determinations regarding the P-STIM mark, including its validity. Counsel also asserted that this Court lacks jurisdiction to compel Biegler to join as a party. Counsel also stated that there was only one other licensee, that counsel he had been in contact with the other licensee, and that the licensee was aware of this lawsuit and had declined to join as a plaintiff. Finally, counsel stated that Biegler would cooperate with discovery, that defendants would not be required to conduct discovery pursuant to the Hague Convention, and that in the event defendants wished to take Ms. Biegler's deposition, Ms. Biegler would travel to the United States for that proceeding.

Based upon the record before the Court, including the various representations made by plaintiff's counsel at the hearing, the Court finds that joinder of absent parties is not warranted. Biegler has assigned all of its rights to protect the P-STIM trademark to plaintiff, and the other licensee does not claim an interest in this litigation. As such, neither Biegler nor the other licensee is a necessary party to this case. Further, based upon the allegations of the SAC, Ms. Biegler's declaration, and the representations of plaintiff's counsel at the hearing, the Court finds that defendants are not at risk of facing multiple lawsuits because Biegler has agreed to be bound by any and all legal determinations made by this Court regarding the mark. Finally, the Court's concerns about the practical difficulties of conducting discovery with regard to Biegler have been addressed by plaintiff's counsel's representations that Biegler will cooperate with discovery as discussed above.

II. Preclusion/preemption of claims based on Federal Food, Drug and Cosmetic Act

Defendants contend that IHS' Lanham Act and state law claims should be dismissed to the extent they are based upon defendants' alleged misuse of an FDA clearance number or violations of the Federal Food, Drug, and Cosmetic Act ("FDCA"). Defendants argue that federal law provides that the FDA has exclusive enforcement authority over the approval of medical devices, and as such, there is no private cause of action for an alleged violation of the FDCA. *See* 21 U.S.C. § 337(a); *Buckman Co. v. Plaintiff's Legal Comm*., 531 U.S. 341, 349 n.4 (2001) (Section 337(a) "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions [of the FDCA]").

Defendants cite *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919 (9th Cir. 2010), for the

proposition that "the federal courts have uniformly established that – especially in the medical device field – claims that require the court to interpret FDA regulations stray too close to the exclusive enforcement domain of the FDA and should not be permitted to proceed." Dkt. 101 at 8:26-9:2. In *PhotoMedex*, the plaintiff alleged that the defendant violated the Lanham Act by falsely advertising a surgical laser as "FDA approved" when it had not in fact been approved. FDA regulations provided that once a medical device had been approved by the FDA, "substantially equivalent" medical devices were also considered approved. 601 F.3d at 925-26. The plaintiff filed an administrative complaint with the FDA alleging that the defendant's new laser was not "substantially equivalent" to an earlier, approved laser. The FDA initially failed to act on the complaint, and eventually determined that the laser at issue was "substantially equivalent" to the earlier laser. *Id*. at 926-27. The plaintiff's Lanham Act claim alleged that prior to the FDA's determination of substantial equivalence, the defendant's representations about FDA approval were false. *Id*. at 927-28. The Ninth Circuit held that under those circumstances, the plaintiff's Lanham Act claim was barred:

> PhotoMedex is not permitted to circumvent the FDA's exclusive enforcement authority by seeking to prove that Defendants violated the FDCA, when the FDA did not reach that conclusion. In a context where the statute and regulations place responsibility in the first instance on the manufacturer to determine whether its device is covered by a previous FDA clearance and permit marketing of the product without an affirmative statement of clearance by the FDA, it is impossible for PhotoMedex to prove that Ra Medical's device had not been cleared by the FDA when the FDA itself did not take that position.

Id. at 928.

In this case, plaintiff responds that "IHS does not bring any claims or causes of action pertaining to the FDA clearance Number, and thus there is no claim preclusion." Dkt. 105 at 9:11-12. Plaintiff argues that "IHS's causes of action do not circumvent the FDA's enforcement authority because IHS is not trying to prove that Defendants violated the Federal Food, Drug, and Cosmetic Act ('FDCA')," but rather that "consumers will believe that Defendants' unapproved products are interchangeable with plaintiff's approved one." Dkt. 105 at 9:15-19. Plaintiff relies on *JHP Pharms., LLC v. Hospira, Inc*., No. CV 13-07460 DDP (JEMx), 2014 WL 4988016, at *4 (C.D. Cal. Oct. 7, 2014), in which the court held that the FDCA did not bar a Lanham Act claim

alleging that the defendant misrepresented its products as being FDA-approved. In *JHP*, the plaintiff alleged, *inter alia*, that the defendant advertised its product as having received FDA approval when it had not, and that the defendant advertised its product as interchangeable with plaintiff's FDA-approved product. *Id*. at *5. The *JHP Pharmaceuticals* court held that these claims were not precluded because "where the issue of FDA approval is straightforward, a Lanham action is viable." *Id*. at *4. Plaintiff argues that, like the plaintiff in *JHP Pharmaceuticals*, it is alleging that defendants falsely represented that their products had FDA approval when they did not (by using plaintiff's 510(K) numbers).

The Court finds that to the extent plaintiff alleges that defendants have falsely represented that they obtained FDA approval for their products, those claims are not precluded or preempted. The Court finds that *PhotoMedex* and another case relied upon by defendants, *Catheter Connections, Inc. v. Ivera Medical Corp*., No. 2:14-cv-70-TC, 2014 WL 3536573 (D. Utah July 17, 2014), are distinguishable on the ground that those cases involved re-approval of new models of existing medical devices.[4] As the *JHP* court held in discussing *Catheter Connections*,

> [R]e-approval of new models of existing medical devices, [is] a circumstance under which the FDA leaves it to the manufacturer, in the first instance, to determine whether it must apply for approval again or assume that the approval carries over. Thus, the manufacturer there could plausibly claim that its product was, in fact, approved, at least until the FDA determined otherwise -- a determination that would, of course, be entirely within the agency's purview. That is obviously very different from the present case, where the Defendants have never had (and do not claim to have had) their products approved in the first place.

JHP Pharms., 2014 WL 4988016, at *6; *see also PhotoMedex*, 601 F.3d at 924-25 ("[F]or example, [if] it was clear that an affirmative statement of approval by the FDA was required before a given product could be marketed and that no such FDA approval had been granted, a Lanham Act claim could be pursued for injuries suffered by a competitor as a result of a false assertion that approval had been granted."); *Par Sterile Products, LLC v. Fresenius Kabi USA*

[4] Further, as the *JHP* court noted, "*PhotoMedex* was the primary case relied on by the lower courts in *POM Wonderful*, and although it was not specifically overruled [by the Supreme Court in *POM Wonderful LLC v. Coca–Cola Co.*, 134 S.Ct. 2228 (2014)], its precedential value may be limited." *JHP Pharms.*, 2014 WL 4988016, at *4. In *POM Wonderful*, the Supreme Court held that the FDCA does not preclude a private party from bringing a Lanham Act claim challenging as misleading a food label that is regulated by the FDCA.

LLC, No. 14 C 3349, 2015 WL 1263041, at *4 (N.D. Ill. Mar. 17, 2015) (holding Lanham Act and state claims not precluded because "Par asserts the specific, particularized claim that a competitor injuriously misrepresents its product as FDA–approved by offering it for sale in certain marketing channels alongside FDA–approved generic drugs. Whether Fresenius is actually deceiving consumers in violation of the Lanham Act by doing so remains in question at this early stage of the proceedings, but the dispute is of the sort with which the Lanham Act is concerned to the extent it involves deception of consumers as to the fact of whether a product carries the imprimatur of FDA approval, not whether the product is safe and effective enough to be approved by the FDA.").

However, as defendants note, the SAC contains allegations that the DyAnsys P-STIM device: (i) "undercuts the FDA regulatory framework," (ii) is "unsafe and hazardous," (iii) is "mislabeled," (iv) is "ineffective," (v) contains "numerous health risks," and (vi) endangers patients and the consuming public. SAC ¶¶ 29, 36. The SAC also alleges that the DyAnsys defendants have imported "ineffective and unsafe products in violation of the federal Food, Drug, and Cosmetic Act." *Id.* at ¶ 29. Plaintiff does not address these allegations in the opposition, and thus it is unclear whether plaintiff intends to pursue these allegations, and if so, the scope of these claims.

Accordingly, the Court DENIES defendants' motion to dismiss plaintiff's Lanham Act claims to the extent plaintiff alleges that defendants falsely represented that their products had FDA approval, when they did not. With respect to plaintiff's other allegations (e.g., ¶¶ 29, 36), the Court GRANTS defendants' motion to dismiss and GRANTS plaintiff leave to amend to clarify the nature and scope of its claims.

III. Noerr-Pennington immunity

Defendants contend that IHS' claims should be dismissed to the extent that they are based upon the DyAnsys defendants' petitioning of CMS and related communications with the government agency, as these are constitutionally-protected activities. Defendants argue that any claims related to their filings before CMS are protected by the First Amendment.

"The Supreme Court has long recognized that for the Petition Clause [of the First

Amendment] to be a meaningful protection of the democratic process, citizens must be immune from some forms of liability for their efforts to persuade government officials to adopt policy or perform their functions in a certain way." *Kottle v. Nw. Kidney Ctrs*., 146 F.3d 1056, 1059 (9th Cir. 1998). This doctrine is referred to as the *Noerr-Pennington* doctrine, which has its origins in the Supreme Court's decision that a party could be immune from liability under the Sherman Act for efforts to influence the legislative or executive branches of government. *See E.R.R. Presidents Conference v. Noerr Motor Freight, Inc*., 365 U.S. 127 (1961); *United Mine Workers v. Pennington*, 381 U.S. 657 (1965). The *Noerr-Pennington* doctrine has been applied to other federal laws beyond those involving antitrust violations. *See, e.g.*, *Sosa v. DIRECTV, Inc*., 437 F.3d 923, 930 (9th Cir. 2006) (applying the *Noerr-Pennington* doctrine to a civil RICO claim and explaining that "[r]ecognizing the constitutional foundation of the doctrine, the Supreme Court has applied *Noerr-Pennington* principles outside the antitrust field").

Plaintiff responds that its allegations related to the CMS petition "are used to show Defendants' overall fraudulent scheme to damage IHS in violation of the Lanham Act and California State law." Dkt. 105 at 11:5-8. Plaintiff asserts that "[e]ven if IHS's allegations did somehow implicate the *Noerr-Pennington* Doctrine, DyAnsys Defendants' CMS petition was a 'sham' petition and would not be protected." *Id*. at 11:9-10.

There is a "sham" exception to the *Noerr-Pennington* doctrine. Sham litigation is described by the Supreme Court as "'private action that is not genuinely aimed at procuring favorable government action' as opposed to 'a valid effort to influence government action.'" *Professional Real Estate Investors, Inc. ("PREI") v. Columbia Pictures Industries*, 508 U.S. 49, 58 (1993) (citing *Allied Tube & Conduit Corp. v. Indian Head, Inc*., 486 U.S. 492, 500, n.4.) The Court in *PREI* outlined a two-part definition of "sham" litigation:

> First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under *Noerr*, and an antitrust claim premised on the sham exception must fail. Only if the challenged exception is objectively meritless may a court examine the litigant's subjective motivation. Under this second part of our definition of sham, the court should focus on whether the baseless lawsuit conceals an attempt to interfere directly with the business relationships of a competitor, through the use [of] the governmental process – as opposed to the outcome of that

process – as an anticompetitive weapon.

PREI, 508 U.S. at 60 (internal quotation marks omitted); *see also Kottle v. Northwest Kidney Centers*, 146 F.3d 1056, 1063 (9th Cir. 1998) (holding heightened pleading standard applies to show that the petitioning activity is objectively baseless).

The Court finds defendants' petitioning of CMS is a constitutionally-protected activity because defendants were seeking relief from a government agency. The Court further finds that plaintiff has not shown that defendants' petitioning constituted a sham. The SAC does not allege any facts to show how the filings before CMS were objectively baseless, and plaintiff's opposition brief does not assert that defendants' filings were objectively baseless. Based upon the record before the Court, it does not appear that plaintiff could allege that defendants' petitioning of CMS and related communications were objectively baseless. Accordingly, the Court DISMISSES plaintiff's claims to the extent that they are based upon the DyAnsys defendants' petitioning of CMS seeking a revision or clarification of the billing codes for plaintiff's product.

IV. Liability of individual defendants

Finally, defendants contend that IHS' claims against the individual defendants should be dismissed because IHS has not pled any facts that would justify holding Nageshwar or Bradford personally liable. The SAC alleges that each individual defendant is "the moving force" behind their companies' allegedly improper conduct. SAC ¶¶ 6, 8. The only other allegation specific to defendant Nageshwar is found in paragraph 27, which alleges that "In January 2013 DyAnsys Defendants improperly submitted to the Centers for Medicare and Medicaid Services ('CMS') a Healthcare Common Procedure Code application for P-STIM (seeking a billing code) in which they misrepresented themselves as the 'manufacturer' of the P-STIM medical device. See Exhibit H hereto, last page, under Defendant Nageshwar's signature. But DyAnsys Defendants have never manufactured the P-STIM medical device, and thus this statement, made to a federal agency, is utterly false." *Id.* ¶ 27.

"A corporate officer or director is, in general, personally liable for all torts which he authorizes or directs or in which he participates, notwithstanding that he acted as an agent of the corporation and not on his own behalf." *Transgo, Inc. v. Ajac Transmission Parts Corp.*, 768 F.2d

1001, 1021 (9th Cir. 1985). The Court agrees with defendants that the SAC does not contain any factual allegations that would provide a basis for holding the individual defendants liable. The allegation that the defendants were the "moving force" behind their companies' improper conduct is conclusory. The only factual allegation specific to Nageshwar -- that he signed an application filed with CMS -- is insufficient on its own to hold Nageshwar for the tortious activity alleged in the SAC.

The Court DISMISSES the claims alleged against the individual defendants and GRANTS plaintiff leave to amend to allege facts in support of individual liability.

CONCLUSION

For the foregoing reasons, defendants' motion is GRANTED IN PART AND DENIED IN PART. Plaintiff shall file an amended complaint by June 5, 2015.

IT IS SO ORDERED.

Dated: May 19, 2015

SUSAN ILLSTON
United States District Judge

United States District Court
Northern District of California