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SENORX, INC.

IN THE UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORP., and HOLOGIC L.P.,

Plaintiffs,

v.

SENORX, INC.,

Defendant.

SENORX, INC.,

Counterclaimant,

v.

HOLOGIC, INC., CYTYC CORP., and HOLOGIC L.P.,

Counterdefendants.

CASE NO.: 08-CV-0133 RMW

DEFENDANT SENORX, INC.'S NOTICE OF MOTION AND MOTION TO DISMISS AND MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF

REDACTED VERSION

Date: June 6, 2008
Time: 9:00 a.m.
Ct. Rm: Courtroom 6, 4th Floor
Judge: Hon. Ronald M. Whyte
Trial Date: Not yet set

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NOTICE OF MOTION AND MOTION TO DISMISS

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD IN THIS MATTER:

PLEASE TAKE NOTICE that on June 6, 2008 at 9:00 a.m., or as soon thereafter as this motion may be heard, Defendant SenoRx, Inc. ("SenoRx") will move to dismiss with prejudice the claims based on the Lanham Act, 15 U.S.C. § 1125 and California's Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200 *et seq.*, and False Advertising Law, Cal. Bus & Prof. Code §§ 17500 *et seq.* set forth in the First Amended Complaint ("FAC"). This motion is made under Federal Rule of Civil Procedure 12(b)(1) and 12(b)(6). SenoRx moves to dismiss with prejudice the Fourth through Sixth Causes of Action on the ground that the FAC fails to state a claim upon which relief may be granted because, *inter alia*, Plaintiffs are not permitted to assert such claims in an effort to interpret and enforce the Federal Food, Drug, and Cosmetic Act ("FDCA"). SenoRx further moves to dismiss the Fifth and Sixth Causes of Action on the grounds that Plaintiffs lack standing to bring them. This motion is based on this Notice of Motion and Motion, the accompanying Memorandum of Points and Authorities, Request for Judicial Notice, and Declaration, the pleadings on file, oral argument of counsel, and such other materials and argument as may be presented in connection with the hearing on the motion.

STATEMENT OF ISSUES

1. Does the FAC state a legally cognizable claim under the Lanham Act, 15 U.S.C. § 1125;

2. Does the FAC state a legally cognizable claim under California's Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200 *et seq.*, and if so, do Plaintiffs have standing to maintain such a claim; and

3. Does the FAC state a legally cognizable claim under California's False Advertising Law, Cal. Bus & Prof. Code §§ 17500 *et seq.*, and if so, do Plaintiffs have standing to maintain such a claim.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

This is an ordinary patent dispute between sophisticated manufacturers of medical devices. Yet, Plaintiffs have recast their patent dispute into a series of scantily-pled federal and state unfair competition claims. The factual predicate alleged for these claims is exceedingly thin, consisting of little more than "labels and conclusions, and a formulaic recitation of the elements of cause[s] of action." *Bell Atl. Corp. v. Twombly*, 127 S.Ct. 1955, 1959 (2007). The legal predicate for Plaintiffs' claims is similarly lacking. Plaintiffs may not rely on unfair competition claims to interpret and enforce the FDCA, and its corresponding regulatory scheme for the marketing and approval of medical devices. Plaintiffs also lack standing to bring such claims under the guise of state unfair competition claims. As such, even at this early stage in the case, Plaintiffs' unfair competition claims should be dismissed. *See id.* (deficiencies in the complaint should "be exposed at the point of minimum expenditure of time and money by the parties and the court").

II. STATEMENT OF FACTS

The current dispute involves the marketing and approval of medical devices used in balloon brachytherapy. Balloon brachytherapy is a safe and effective method for treating early-stage breast cancer. It involves delivery of radiation from a medical device implanted in the breast cavity. *See* FAC ¶ 13. "Owing to the proximity of the radiation source, brachytherapy offers the advantage of delivering a more localized dose to the target tissue region." FAC, Exhibit ("Ex.") B at 7.

Plaintiffs manufacture and sell a balloon brachytherapy device known as the MammoSite® Radiation Therapy System ("MammoSite"). *See* FAC ¶ 11. The device consists of a double-lumen catheter embedded in an inflatable balloon. The device must be implanted into the breast cavity. Following implantation, the first lumen inflates the balloon with sterile water and contrast material. The expansion of the balloon fills the surgical cavity and compresses the surrounding breast tissue. The second lumen then delivers a high dose of radiation, irradiating cancerous tissue.

Because the MammoSite has only one lumen capable of delivering radiation, there are inherent limitations in its use. For example, the MammoSite cannot deliver radiation to cancerous tissue in close proximity to the skin or ribs. The instruction for use ("IFU") that accompany the MammoSite state: "Do not deliver radiation if the minimum distance from the balloon surface to the skin surface is less than 5 mm. . . ." FAC, Ex. E at 7.[1] The IFU also warns physicians that "a minimum distance of 7 mm from balloon surface to skin surface is recommended." *Id.; see also id.* at 27-31. Therefore, once implanted, the MammoSite may become unsuitable for treatment and must be explanted because of inadequate tissue thickness.

Recognizing a business opportunity in this and other inherent limitations in the MammoSite, SenoRx developed the Contura™ Multi-Lumen Balloon ("Contura"). Unlike the MammoSite, the Contura has multiple lumens capable of delivering radiation. *See* FAC ¶ 24. These lumens enable physicians to more precisely deliver radiation to cancerous tissue, and thereby prescribe balloon brachytherapy to a larger patient population.

Before the Contura could be prescribed for human use, SenoRx was obligated to obtain approval from the United States Food & Drug Administration ("FDA"). The FDA is charged with "promot[ing] the public health by promptly and efficiently . . . taking appropriate action on the marketing of regulated products in a timely manner" and "protect[ing] the public health by ensuring . . . the safety and effectiveness of devices intended for human use." 21 U.S.C. § 393(b)(1), (b)(2)(C). In this capacity, the FDA regulates and must approve the introduction of all new medical devices. *Id.* § 360e.

Manufacturers intending to market a medical device must first obtain pre-market approval. Since 1976, it has been unlawful to sell a new medical device without FDA approval. However, the Medical Device Amendments ("MDA") to the FDCA have grandfather provisions covering devices lawfully sold on or before May 28, 1976, that are "substantially equivalent" to

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[1] The Court may consider documents attached to complaint or documents incorporated by reference in the complaint without converting motion to dismiss into one for summary judgment. *See United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003).

them. 21 U.S.C. § 360c(f)(1)(A)(ii). "Substantial equivalence" means, *inter alia*, that a device "has the same intended use as the predicate device" and the device, even with different technological characteristics, "is as safe and effective as a legally marketed device." *Id.* § 363c(i)(1)(A)(ii). These provisions "set forth a comprehensive scheme for determining whether an applicant has demonstrated that a product is substantially equivalent to a predicate device." *Buchman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348 (2001).

Relying on the FDCA grandfather provisions, SenoRx asked the FDA to approve the Contura because it is "substantially equivalent" to two other predicate brachytherapy devices, one of which was the MammoSite. *See* FAC ¶ 19. The FDA considered SenoRx's request, and approved the Contura for use in brachytherapy on May 23, 2007. *See id.* ¶ 20. Like the MammoSite, the approved indications for the Contura provide the device "is intended to provide brachytherapy when the physician chooses to deliver intercavity radiation to the surgical margins following lumpectomy for breast cancer." *See id.* Ex. D at 6 (Contura indications for use); *see also id.* Ex. E at 7 (MammoSite indications for use). However, unlike the MammoSite device, the FDA did not require SenoRx to include a contraindication that precludes the delivery of radiation "if the minimum distance from the balloon surface to the skin surface is less than 5 mm. . . ." FAC, Ex. E at 7.

After receiving FDA approval, SenoRx began its commercial launch of the Contura. The commercial launch was followed by Plaintiffs filing their current claims for unfair competition under the Lanham Act, 15 U.S.C. § 1125 and California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200 *et seq.*, and False Advertising Law ("FAL"), Cal. Bus & Prof. Code §§ 17500 *et seq.* The core allegation that underlies all of these claims is that SenoRx fraudulently marketed the Contura by falsely implying the FDA approved the device for brachytherapy treatment of "superficial excision margins in close proximity to the surface of the skin." FAC ¶¶ 46, 59, 73; *see also id.* ¶¶ 51, 65, 79 (alleging that SenoRx makes misleading representations "with the specific intent that these representations deceive and mislead consumers and potential consumers of brachytherapy products"); *id.* ¶ 71 (alleging that "SenoRx

purposefully and intentionally engaged in unfair, deceptive, untrue, and/or misleading advertising").

Plaintiffs' unfair competition claims are based on a series of inaccurate allegations about SenoRx's marketing of the Contura, as well as erroneous notions about FDA's approval of the device.[2] For the purpose of this motion only, however, Plaintiffs' factual contentions are assumed to be correct. Even with these assumptions, Plaintiffs' claims are legally barred, *see* Fed. R. Civ. P. 12(b)(6), and Plaintiffs lack standing to bring them, *see* Fed. R. Civ. P. 12(b)(1).

III. SUMMARY OF LEGAL STANDARDS GOVERNING THIS MOTION

In deciding a motion under Rule 12(b)(6), "all material allegations of the complaint are accepted as true, as well as all reasonable inferences to be drawn from them." *Cahill v. Liberty Mut. Ins. Co.*, 80 F.3d 336, 338 (9th Cir. 1996). However, to survive a motion to dismiss, the FAC must contain more than labels, legal conclusions, and a formulaic recitation of a cause of action's elements. *Bell Atlantic Corp.*, 127 S.Ct. at 1959; *Papasan v. Allain*, 478 U.S. 265, 286 (1986). Additionally, where as here, Plaintiffs claim SenoRx engaged in fraudulent marketing practices, Federal Rule of Civil Procedure 9(b) requires them to plead facts concerning the alleged fraud with specificity, including an account of the "time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentations." *Edwards v. Marin Park, Inc.*, 356 F.3d 1058, 1066 (9th Cir. 2004) (citation omitted); *see also Vess v. Ciba-Geigy Corp.*, 317 F.3d 1097, 1103-04 (9th Cir. 2003) (Rule 9(b) applies to "averments of fraud" even if fraud is not an essential element of the claim and the claim is based on state law); *Stickrath v. Globalstar, Inc.*, 527 F. Supp. 2d 992, 997(N.D. Cal. 2007) (applying 9(b) to false advertising claim); *Faigman v. AT & T Mobility LLC*, NO. C 06-04622 MHP, 2007 WL 2088561, *3 (N.D. Cal. Jul 18, 2007) (applying 9(b) to unfair competition claim); *Collegenet, Inc. v. XAP Corp.*, No.

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[2] Because a partial motion to dismiss extends the time to answer, SenoRx has not answered Plaintiffs' patent law claims. *See Pestube Sys., Inc. v. HomeTeam Pest Defense*, LLC., No. Civ-05-2832-PHX-MHM, 2006 WL 1441014, at *7 (D. Ariz. May 24, 2006) (pending motion to dismiss tolls the time to time to respond to all claims); *Batdorf v. Trans Union*, No. C 00-0501 CRB, 2000 WL 635455, at *5 (N.D. Cal. May 8, 2000) (Defendant not required to file answer to claims it was not moving to dismiss while motion to dismiss is pending).

CV-03-1229-HU, 2004 WL 2303506, *4 (D. Or. Oct. 12, 2004) (applying Rule 9(b) to a Lanham Act claim); *Accord Nat'l Ass'n for Advancement of Psychoanalysis v. California Bd. of Psychology*, 228 F.3d 1043, 1049 (9th Cir. 2000) ("Conclusory allegations of law and unwarranted inferences are insufficient to defeat a motion to dismiss for failure to state a claim."). Here, Plaintiffs fail to satisfy these pleading requirements.

IV. ARGUMENT

A. Plaintiffs' Lanham Act Claim Fails as a Matter of Law.

Plaintiffs wrongly claim SenoRx engaged in false and deceptive advertising in violation of § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B). FAC ¶ 52. Section 43(a) authorizes suit against those who make false and deceptive statements in a commercial advertisement about their own or plaintiff's product. *See Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997); *Cook, Perkiss & Liehe, Inc. v. N. Cal. Collection Serv. Inc.*, 911 F.2d 242, 244 (9th Cir. 1990). To maintain such a claim, Plaintiffs must establish: (1) SenoRx made false statements of fact when it advertised the Contura; (2) SenoRx's statements deceived or had the tendency to deceive a substantial segment of SenoRx's audience; (3) the deception was material; (4) SenoRx caused its false statements to enter interstate commerce; and (5) Plaintiffs have been or are likely to be injured. *See Jarrow Formulas, Inc. v. Nutrition Now, Inc.*, 304 F.3d 829, 834 n.4 (9th Cir. 2002) (citations omitted); *Rice v. Fox Broad. Co.*, 330 F.3d 1170, 1180 (9th Cir. 2003). Plaintiffs do not, and cannot allege, *inter alia*, the first and second elements.

1. Plaintiffs Fail To Allege A Cognizable Claim of Falsity.

To allege falsity, Plaintiffs must identify the purportedly false statements and show those statements are either literally false or, if true, likely to mislead or confuse consumers. *See Southland Sod Farms*, 108 F.3d at 1139. Plaintiffs attempt to satisfy that obligation by alleging SenoRx asserts in its customer presentations that "the Contura™ Multi-Lumen Balloon is superior to the MammoSite® Applicator radiation treatment of surgical margins in close

proximity to (at, for example, less than 5 mm from) the surface of the skin." *Id.* ¶¶ 44, 45, 46.[3] However, the only statements Plaintiffs identify to support that allegation are contained in a document attached to the FAC as Exhibit G. *See id.* ¶¶ 44, 45, 58, 59, 72, 73, 78, 79. Plaintiffs claim "on information and belief," that SenoRx relies on statements contained in Exhibit G to compare the MammoSite® Applicator and the Contura™." FAC ¶ 44. As an initial matter, Plaintiffs' allegation is insufficient, as allegations of fraud based on information and belief usually do not satisfy the degree of particularity required under Rule 9(b). *See Wool v. Tandem Computers, Inc.*, 818 F.2d 1433, 1439 (9th Cir. 1987); *Competitive Techs. v. Fujitsu Ltd.*, 286 F. Supp. 2d 1118, 1148 (N.D. Cal. 2003). Moreover, Exhibit G references the MammoSite in only two places. It states: (1) "2mm Contura skin distance gets about the same dose as 8mm skin distance (MammoSite);" and (2) "3mm skin bridge: still getting 112% dose: Equivalent to 9mm skin (MammoSite)." Ex. G at 12, 15 (parenthesis in original).[4]

Plaintiffs do not allege these statements are literally false. Nor do they allege SenoRx affirmatively stated the FDA approved the Conutra for such uses. Rather, Plaintiffs argue SenoRx "has no brachytherapy device which is FDA cleared or approved for treatment of superficial excision margins in close proximity to the surface of the skin." FAC ¶ 46. Consequently, Plaintiffs reason the statements contained in Exhibit G are misleading because they (1) imply SenoRx has obtained the requisite FDA approval; or (2) omit that SenoRx lacks such approval. *See* FAC ¶¶ 46, 47; *see also id.* ¶ 48 (SenoRx's statements will "confuse and mislead, a substantial number of persons . . . into believing . . . the Contura™ Multi-Lumen

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[3] "[A]dvertising which merely states in general terms that one product is superior is not actionable." *Cook, Perkiss & Liehe, Inc. v. Northern Ca. Collection Serv. Inc.*, 911 F.2d 242, 246 (9th Cir. 1990); *see also Freecycle Network, Inc. v. Oey*, 505 F.3d 898, 904 (9th Cir. 2007) ("Statements of opinion are not generally actionable under the Lanham Act."(quoting *Coastal Abstract Serv., Inc. v. First Am. Title Ins. Co.*, 173 F.3d 725, 731 (9th Cir. 1999))).

[4] To the extent Plaintiffs claim SenoRx's advertisements explicitly or implicitly asserts a claim of product superiority based on scientifically reliable data, Plaintiffs have not identified any such claims or data. *See* FAC ¶¶ 45, 59, 73. Moreover, Plaintiffs base their claims of unsubstantiated data on their belief that SenoRx has not received FDA clearance or approval for the Contura to be used to treat skin distances of less than 5 mm. *See id.* ¶¶ 46, 60, 74.

Balloon is FDA cleared and/or approved for administration of radiation treatment to superficial resection cavities near the surface of the skin").[5]

The FDA approval SenoRx allegedly lacks can be obtained pursuant to (and only because of) FDCA and FDA regulations. Where, as here, Plaintiffs' allegations of implied falsity depend on an application or interpretation of those regulations, their Lahman Act claim cannot stand. The Lanham Act simply does not provide Plaintiffs with a vehicle for enforcing FDCA and FDA regulations. Rather, "[t]he FDCA 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: '[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.'" *Buchman Co.*, 531 U.S. at 349 n.4 (quoting 21 U.S.C. § 337(a)).

To that end, Congress vested the FDA and the United States Department of Justice ("DOJ") with a variety of enforcement options that allow a measured response to regulatory violations. For instance, the FDA and DOJ are empowered to investigate suspected FDCA violations, including off labeled promotion, *see* 21 U.S.C. § 372, and private citizens may report such wrongdoing and petition the FDA to take action. *See* 21 C.F.R. § 10.30; *see Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 n.10 (3d Cir. 1990) (Plaintiff is "free to petition the FDA to investigate . . . alleged labeling violations") (citations omitted). The FDA and DOJ, in turn, may respond to improper labeling or promotion by seeking injunctive relief, 21 U.S.C. § 332, and civil penalties, 21 U.S.C. § 33(f)(1)(A); seizing the device, 21 U.S.C. § 334(a)(2)(D); and pursuing criminal sanctions, 21 U.S.C. § 222(a). "This flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives" pertaining to the approval, use, promotion, and labeling of medical devices. *Buchman Co.*, 531 U.S. at 349.

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[5] Plaintiffs wrongly equate lack of approval with disapproval. *See Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 67 (D.D.C. 1998) ("[t]he fact that [a use] is not an approved indication should not be viewed as some sort of determination by FDA that the use is inappropriate or is ineffective."), *vacated in part on other grounds*, 202 F.3d 331 (D.C. Cir. 2000)

Plaintiffs cannot displace the FDCA's and FDA's statutory and regulatory framework for medical devices through § 43(a) of the Lanham Act. *See, e.g., Dial A Car, Inc. v. Transp., Inc.*, 82 F.3d 484, 490 (D.C. Cir. 1996) (Lanham Act cannot be used as "back-door method" of interpreting and enforcing administrative regulations); *Sandoz Pharm. Corp.*, 902 F.2d at 228-29 ("[W]hat the [FDCA] . . . do[es] not create directly, the Lanham Act does not create indirectly."); *Rita Med. Sys., Inc. v. Resect Med., Inc.*, No. C 05-03291 WHA, 2006 WL 2038328, at *3 (N.D. Cal. Jul. 17, 2006) ("[T]he Lanham Act cannot be used as a circuitous route to challenge determinations of the FDA."). Yet that is precisely what Plaintiffs seek to do. Among the issues raised by Plaintiffs' Lanham Act claim are whether the FDA has approved the Contura for the use described by Plaintiffs and, if not, whether SenoRx was obligated to file a new application with the FDA before it could make statements contained in Exhibit G. Essentially, Plaintiffs complain about off label promotion, which is squarely within the enforcement authority of the FDA and DOJ.

First, Plaintiffs' Lanham Act claim assumes the FDA did not "clear[] or approve[] [the Contura] for treatment of superficial excision margins in close proximity to the surface of the skin." FAC ¶¶ 46, 47. To support that assumption, Plaintiffs rely on the IFU for the Contura, which allegedly "warns against specific use with a balloon surface-to-skin surface distance of less than 5 mm." *Id.* ¶ 47. Such reliance is misplaced. The warning contained in the IFU reads: "The breast cavity must be imaged *before implantation* to insure the applicator will fit appropriately. Do not use if the cavity is too small or if a skin surface to balloon surface distance of less than 5 mm *will result*." *Id.*, Ex. F at 2 (emphasis added). Fairly read, the warning provides guidance to the surgeon at the time of applicator implantation. During radiation delivery, which may occur two to five days after implantation, the skin distance may fall below 5 mm due to tissue relaxation, balloon movement, etc. With the Contura, physicians do not have to explant the device, and may safely deliver radiation doses at skin distances below 5 mm.

Plaintiffs have a contrary view and interpret the warning expansively to prohibit not only implantation of the Contura when a skin distance of less than 5 mm will result, but also to prevent radiation doses from being applied to such skin distances. Plaintiffs' expansive reading

of the IFU, however, ignores obvious technological differences between the Contura and the MammoSite. The MammoSite has only one lumen capable of delivering radiation. *See* FAC, Ex. E at 23. In a single-lumen radiation device, the radiation dose to the skin has fixed radial distance. *See, e.g., id.*, Ex. A at 5 ("[I]t is possible to deliver a desired radiation dose at a predetermined radial distance from a source of radioactivity"). For example, at 5 mm, the dose to the skin is 143%. *See id.*, Ex. E at 19. The same is not true for multi-lumen devices. Multi-lumen devices offer the flexibility of dose control through multiple lumens. *See id.*, Ex. G at 4.

Consequently, when it approved the Contura, the FDA did not require SenoRx to include the contraindication contained in the MammoSite IFU, which precludes physicians from "*deliver[ing] radiation* if the minimum distance from the balloon surface to the skin surface is less than 5 mm." (emphasis added). *Compar*e FAC, Ex. E. at 7 *with* FAC, Ex. F at 2; *see e.g.* 21 C.F.R. § 201.57 (contraindications "describe any situations in which the drug should not be used because the risk of use (e.g., certain potentially fatal adverse reactions) clearly outweighs any possible therapeutic benefit."); *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1386 n.5 (4th Cir. 1995) (a contraindication is a direction to the physician not to use the drug).

Because the MammoSite is contraindicated for radiation delivery to skin distances of less than 5 mm and the Contura is not, Plaintiffs' reading of the Contura IFU to exclude such use is at best subject to further FDA consideration, and at worst wrong. *See Southland Sod Farms*, 108 F.3d at 1139 ("When evaluating whether an advertising claim is literally false, the claim must always be analyzed in its full context."). Nonetheless, Plaintiffs seek, *inter alia*, to have the Contura removed from the market by asking the Court to second guess the FDA and interpret and apply FDCA and FDA regulations consistent with their reading of the Contura IFU.

The Court should not do so. The FDA has not yet issued guidance or otherwise resolved the question raised by Plaintiffs' readings of the Contura label.[6] [redacted]

[6] That is not to say the FDA interpreted the Contrua IFU as Plaintiffs suggest or failed to consider the appropriateness of the Contura device for the described use. For example, a congressional investigation into FDA procedures revealed that, "[o]ver the years, FDA has made premarket regulatory decisions based on uses for devices that are unrelated to the intended uses set forth in labeling." *See* S. REP. NO. 105-43, 105th Cong., 1st Sess. 27 (1997). The FDA's (continued...)

[redacted]

Second, Plaintiffs' Lanham Act claim alternatively assumes the Contura cannot be marketed for radiation delivery for skin distances less than 5 mm unless and until SenoRx files a new application for approval with the FDA. Once the FDA clears a medical device for sale, the manufacturer may modify the device without obtaining additional approval. Modifications encompass, *inter alia*, changes in the way a device is promoted. *See* 21 C.F.R. 807.81; *see also United States v. Prigmore*, 243 F.3d 1, 20 (1st Cir. 2001) (manufacturer must take into account

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practice of informally reviewing uses other than those to be included on labeling invalidates any assumption that, simply because a use does not appear on FDA labeling, a use has received no regulatory review.

[7] The Court may consider [redacted] without converting the motion into one for summary judgment. *See Intri-Plex Techs., Inc. v. Crest Group, Inc.*, 499 F.3d 1048, 1052 (9th Cir. 2007) ("[a] court may take judicial notice of 'matters of public record' without converting a motion to dismiss into a motion for summary judgment, as long as the facts noticed are not subject to reasonable dispute."); *see also Abrego Abrego v. The Dow Chem. Co*., 443 F.3d 676, 681 (9th Cir. 2006). ("a district court ruling on a motion to dismiss may consider a document the authenticity of which is not contested, and upon which the plaintiff's complaint necessarily relies"); *superseded by statute on other grounds by,* 443 F.3d 676, 681 (9th Cir. 2006).

off label, though promoted uses in determining whether a modification affects safety or effectiveness). Thus, if the statements contained in Exhibit G evidence unapproved uses of the Contura, as Plaintiffs claim, it is not clear additional FDA approval is necessary. The line between a modification where no approval needed and one that requires independent approval is within the exclusive province of the federal government. *See, e.g.*, 71 Fed. Reg. 3922, 2934 ("the determination whether labeling revisions are necessary is, in the end, squarely and solely FDA's, under the [FDCA]"); *see also* 21 C.F.R. § 807.81. There are two principal inquiries: first, whether the modification "significantly affect[s] the safety or effectiveness of the device" and, second, whether there is a "major change or modification in the intended use of the device." 21 C.F.R. § 807.81(a)(3). Phrases such as "significantly affect" and "major change . . . in the intended use" are not self-defining and the FDA has not applied them to resolve questions raised by Plaintiffs' interpretation of the Contura warning. Accordingly, even under Plaintiffs' reading of the Contrura IFU, an open question remains concerning whether the statements in Exhibit G require SenoRx to obtain additional approvals from the FDA. That question should be answered in the first instance by the FDA.

* * *

Absent clear and unambiguous rulings from the FDA, Plaintiffs employ the Lanham Act to disambiguate FDCA and FDA regulations and to enforce their preferred interpretation of the Contura warning. That is improper. *See PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 113 (2d Cir. 1997) (Lanham Act claim that product is sold without proper FDA approval is an improper attempt to privately enforce FDCA); *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993) (dismissing for failure to state a claim plaintiff's "ingenious" attempt to "use the Lanham Act as a vehicle by which to enforce the" FDCA); *Sandoz Pharm. Corp.*, 902 F.2d at 228-29 (rejecting Lanham Act claim that manufacture failed to comply with FDA labeling requirements); *Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharm., Inc.*, No. 07-CV-642, 2008 WL 582738 (E.D. Wis. Feb. 29, 2008) (dismissing Lanham Act claims based on violations of FDA labeling requirements); *Photomedex, Inc. v. RA Med. Sys., Inc.*, No. 04CV24 JLS (CAB), 2007 WL 3203039, at **2-4 (S.D. Cal. Oct. 29, 2007) (rejecting Lanham Act claim

alleging defendant improperly branded medical device as "FDA Approved"); *Rita Med. Sys., Inc.*, No. C 05-03291 WHA, 2006 WL 2038328, at *3 (Lanham Act claim impermissibly implicated review of FDA authorization determination); *Autin v. Solvay Phram., Inc.*, No. 05-2213 MA/AN, 2006 WL 889423, at *3-4 (W.D. Tenn. Mar. 31, 2006) (granting motion to dismiss Lanham Act claims based on implied FDA approval); *Merck & Co. v. Mediplan Health Consulting, Inc.*, 425 F. Supp. 2d 402, 417 (SDNY 2006) (same); *Creagri, Inc. v. USANA Health Sci.*, No. 03-3216 MMC, 2005 WL 181886, at * 7 (N.D. Cal. Jan. 26, 2005) ("the Court lacks jurisdiction to consider a Lanham Act claim premised on a violation of FDA regulations"); *Ethex Corp. v. First Horizon Pharm. Corp.*, 228 F. Supp. 2d 1048, 1054-55 (E.D. Mo. 2002) (refusing to allow plaintiffs state a Lanham Act claim based on implicit representations of FDA approval); *Braintree Labs., Inc. v. NephroTech, Inc.*, No. 96-2459-JWL, 1997 WL 94237, at *6-7 (D. Kan. Feb. 26, 1997) (Plaintiff may not maintain a Lanham Act claim alleging defendant failed to disclose the FDA has not approved its product); *Barr Labs, Inc. v. Quantum Mechanics, Inc.*, No. 90-CV-4406, 1994 WL 1743983, at *9 (E.D.N.Y. Feb. 7, 1994) (dismissing Lanham Act claim that alleged defendants falsely represented or implied drugs had been approved by FDA). "[S]uch a claim would allow a private litigant to interfere with the FDA's own investigatory time-table and prosecutorial decision-making . . . [and] . . . would force the Court to rule directly on the legality of . . . conduct before the FDA has had a chance to do so." *Summit Tech., Inc.*, 922 F. Supp. at 306.

2. Plaintiffs' Claim That SenoRx Made Misleading Statements Is Not Plausible.

Plaintiffs assert the alleged representations in Exhibit G are confusing or misleading to a substantial number of persons because they indicate "the Contura™ Multi-Lumen Balloon is FDA cleared and/or approved for administration of radiation treatment to superficial resection cavities near the surface of the skin." FAC ¶¶ 44, 45, 48. There are several problems with that claim.

First, the representations on which Plaintiffs' rely do not imply FDA approval. On their face, the statements contained in Exhibit G do not suggest the FDA considered or approved the Contura for any particular purpose. *See id.* ¶¶ 44, 45, 58, 59, 72, 73, 78, 79; *see Wright v. Oregon*

Metallurgical Corp., 360 F.3d 1090, 1096 (9th Cir. 2004) (court is not required to accept as true conclusory allegations which "are contradicted by documents referred to in the complaint."). Rather, the references state only that: (1) "2mm Contura skin distance gets about the same dose as 8mm skin distance (MammoSite)"; and (2) "3mm skin bridge: still getting 112% dose: Equivalent to 9mm skin (Mammosite)." FAC, Ex. G at 12, 15 (parenthesis original).[8]

Second, Plaintiffs' claims are undermined by the sophistication of those who purchase and use the Contura. The Contura can only be purchased and prescribed by licensed physicians. *See id.*, Ex. D at 6 ("Prescription Use"); *Id.*, Ex. F at 2 (""Federal (USA) law restricts this device to sale by or on the order of a physician"). Physicians must routinely decide whether to use medical devices in ways that have not been approved by the FDA. That practice is not only legal, but is a common and integral feature of medical practice. *See Buchman Co.*, 531 U.S. at 1082 ("off-label usage of medical devices . . . is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine."); *Washington Legal Found. v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000) ("neither Congress nor the FDA has attempted to regulate the off-label use of [devices] by doctors or consumers"). Indeed, FDCA and FDA regulations expressly authorize physicians to use medical devices in unapproved ways: "Nothing in this chapter shall be construed to limit or interfere with the authority of a healthcare practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease . . . ." 21 U.S.C. § 396 (emphasis added). It is inconceivable that sophisticated physicians familiar with the Contura label would be confused about what the FDA has and has not approved by this factual information in Exhibit G.

Third, claims that information pertaining to unapproved uses falsely implies FDA approval is inconsistent with FDCA and FDA regulations. Those regulations permit manufacturers to disseminate information concerning unapproved uses in a variety of circumstances. For instance,

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[8] To the extent Plaintiffs base their claims on the notion that "the "Contura™ device is capable of treating a patient base (as for example, those patients with superficial excision cavities close to the skin surface) for whom treatment with the MammoSite® Applicator is contraindicated," FAC ¶¶ 50, 64, 78, that statement is true. *See* discussion *supra* at 3; 9-10.

FDCA and FDA regulations allow manufacturers to distribute information concerning unapproved uses in response to inquiries from physicians, *see* 21 U.S.C.A. § 360aaa-6, and by providing information the FDA deems scientifically reliable. *See* 21 U.S.C.A. § 360aaa.[9] That distribution cannot, without more, imply FDA approval or be deemed "inherently misleading." *See Washington Legal Found.*, 13 F. Supp. 2d at 67 (information pertaining to off-label claims is not "untruthful" or "inherently misleading" merely because the FDA has not yet had the opportunity to evaluate the claim). Otherwise, device manufacturers that comply with those FDCA and FDA regulations permitting the dissemination of Off-Label Use information, in whole or in part, to influence the purchasing decisions of their customers, subject themselves to a claim of false advertising under the Lanham Act. *See Coastal Abstract Serv., Inc. v. First Am. Title Ins. Co.*, 173 F.3d 725, 735 (9th Cir. 1999) (commercial advertisement under the Lanham Act includes any commercial speech made for the purpose of influencing an audience to buy goods or services).

Finally, Plaintiffs' claim is internally inconsistent. On the one hand, Plaintiffs claim statements in Exhibit G will mislead physicians into believing the "the Contura™ Multi-Lumen Balloon is FDA cleared and/or approved for administration of radiation treatment to superficial resection cavities near the surface of the skin [(less than 5 mm)]." FAC ¶¶ 45, 48. On the other hand, Plaintiffs allege the Contura IFU, "explicitly warns against specific use with a balloon surface-to-skin surface distance of less than 5 mm." FAC ¶ 47. Physicians are presumed to read the warnings accompanying a medical device that delivers radiation after implantation in the body. *See also Freeman v. Time, Inc.*, 68 F.3d 285, 290 (9th Cir. 1995) ("unless particularly gullible consumers are targeted, a reasonable person may expect others to behave reasonably as well"). Therefore, if Plaintiffs' reading of the Contura IFU is correct – which it is not – any physician using the Contura in skin distances of less than 5 mm would know he or she was violating an "explicit[] warn[ing]" and thereby making an unapproved use of the device. *See*

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[9] Even if the FDA determines a manufacturer has not complied with 21 U.S.C.A. § 360aaa, the FDA may still permit the manufacture to disseminate information concerning the safety, effectiveness, or benefit of a use not described in the approved labeling of a device. *See Washington Legal Found.*, 202 F.3d at 335-36.

Kincer v. Danek Medical, Inc., No. 96-3240, 1999 WL 1866402, at *7 (W.D. Tenn. Apr. 19, 1999). Consequently, Plaintiffs cannot plausibly claim statements contained in Exhibit G "actually deceived or had the tendency to deceive a substantial segment of its audience" into believing the Contura device had been approved for uses the IFU "explicitly warns against." FAC ¶ 47; *Newcal Indus., Inc. v. Ikon Office Solution*, 513 F.3d 1038, 1052 (9th Cir. 2008).

B. The Court Lacks Jurisdiction To Consider Plaintiffs' State Law Claims.

A dismissal of Plaintiffs' Lanham Act claim divests the Court of original and pendant jurisdiction over Plaintiffs' UCL and FAL claims. First, state law claims based in whole or in part on regulations for which Congress has determined there is no private, federal cause of action, do not state a claim "arising under the Constitution, laws, or treaties of the United States.'" *Merrell Dow Pharm. v. Thompson*, 478 U.S. 804, 817 (1986) (quoting 28 U.S.C. § 1331); *see also Webb v. Smart Document Solutions, LLC*, 499 F.3d 1078, 1083 (9th Cir. 2007); *Utley v. Varian Assoc., Inc.*, 811 F.2d 1279, 1282-83 (9th Cir. 1987).

Second, Plaintiffs cannot establish pendant jurisdiction. Pendant jurisdiction is proper only when state and federal claims "derive from a common nucleus of operative fact." *Mendoza v. Zirkle Fruit Co.*, 301 F.3d 1163, 1174 (9th Cir. 2002). Here, if the Lanham Act claim is dismissed, the only remaining federal claims will involve alleged patent infringement. *See* FAC ¶¶ 27, 33, 39. The facts pertaining to those claims are separate and irrelevant to facts involved in Plaintiffs' UCL and FAL claims. The former requires an interpretation of the scope and meaning of the patented claim followed by a comparison of the accused product to that claim. *See Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1320 (Fed. Cir. 2003). The latter requires a determination of whether SenoRx had FDA approval to market the device for narrow skin distances and if not, whether SenoRx falsely implied FDA approval of that particular use. Because Plaintiffs' federal patent law claims are separately maintainable and determinable without reference to the facts alleged for the state court claims, the Court lacks pendent jurisdiction over the state law claims. *See Microthin.com, Inc. v. Siliconezone USA, LLC*, NO. 06 C 1522, 2006 WL 3302825, at * 4 (N.D. Ill. Nov. 14, 2006) (tort claims do not arise out of same operative facts as infringement claim); *Global Maintech Corp. v. AIG Techs., Inc.*, No. Civ. 04-4638(JNE/SRN),

2006 WL 354224, at *6 (D. Minn. Feb. 15, 2006) (breach of contract claims do not arise out of same operative facts as infringement claim); *Trilithic, Inc. v. Wavetek U.S. Inc.*, 6 F. Supp. 2d 803, 806 (S.D. Ind. 1998) (same).[10]

C. Plaintiffs' Claims Under the UCL and FAL Fail as a Matter of Law.

Plaintiffs' UCL and FAL claims are identical to their Lanham Act claim. They are based on the same facts and should be dismissed for the same reasons. *See Japan Telecom, Inc. v. Japan Telecom Am., Inc.*, 287 F.3d 866, 875 (9th Cir. 2002) (plaintiff's "California unfair competition claim fails because its related Lanham Act claims fail"); *Denbicare U.S.A., Inc. v. Toys "R" Us, Inc.*, 84 F.3d 1143, 1152-53 (9th Cir. 1996) (dismissal of plaintiff's § 17200 and § 17500 claims were proper since plaintiff's Lanham Act claim was properly dismissed); *Cleary v. News Corp.*, 30 F.3d 1255, 1262-63 (9th Cir. 1994) (actions pursuant to Cal. Bus. & Prof. Code § 17200 are "substantially congruent" to claims made under the Lanham Act); *CKE Rest. v. Jack in the Box, Inc.*, 494 F. Supp. 2d 1139, 1146 (C.D. Cal. 2007) (same); *Walker & Zanger, Inc. v. Paragon Indus., Inc.*, No. C-04-1946 VRW, 2007 WL 1302980, at *11 (N.D. Cal. May 3, 2007) (same); *see also Chabner v. United of Omaha Life Ins. Co.*, 225 F.3d 1042, 1048 (9th Cir. 2000) ("A court may not allow a plaintiff to plead around an absolute bar to relief simply by recasting the cause of action as one for unfair competition."); *Hartless v. Clorox Co.*, No. Civ. 06CV2705JAHCAB, 2007 WL 3245260, at **3-4 (S.D. Cal. Nov. 2, 2007) (where private rights of action to enforce a statute have been expressly barred by Congress, that statute may not serve as a predicate for an unfair competition claim.); *RA Med. Sys. Inc. v. Photomedex, Inc.*, No. 06CV1479JLS CAB, 2007 WL 3203033, at *4 (S.D. Cal. Oct. 29, 2007) (dismissing state unfair competition claims based on defective Lanham Act claim for marketing drug contrary to FDA

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[10] Supplemental jurisdiction is a doctrine of discretion, not of a plaintiff's right. See *City of Chicago v. Int'l College of Surgeons*, 522 U.S. 156, 172 (1997). This Court may decline to exercise supplemental jurisdiction over a state law claim if, *inter alia*, the claim raises a novel or complex issue of state law. Here, the Court would be required to determine how California courts would rule on claims that require referring to, or applying, FDCA and FDA regulations despite an express prohibition by Congress on private causes of action to enforce those regulations. *See, e.g., In re Farm Raised Salmon Cases*, 42 Cal. 4th 1077, 72 Cal. Rptr. 3d 112, 175 P.3d 1170 (2008) ("plaintiffs' claims in this case do not require referring to, or applying, the FDCA").

approval); *Summit Tech., Inc.*, 922 F. Supp. at 306 (dismissing state unfair competition claims based on defective Lanham Act claim for marketing medical device contrary to FDA approval). Additionally, Plaintiffs' UCL and FAL claims fail because Plaintiffs lack standing to bring them and fail to allege the necessary facts to support them.

1. Plaintiffs' Lack Standing To Bring UCL and FAL Claims.

Standing to bring a private claim under the UCL and FAL is limited to "any person who has suffered injury in fact and has lost money or property as a result of" such unfair competition or false advertising. *See* Cal. Bus. & Prof. Code §§ 17204 & 17535; *see also CA for Disability Rights v. Mervyn's, LLC*, 39 Cal.4th 223, 227, 46 Cal.Rptr.3d 57, 138 P.3d 207 (2006) (a private person has standing to sue only if he or she "has suffered injury in fact and has lost money or property as a result of such unfair competition."); *Hall v. Time Inc.,* 158 Cal.App.4th 847, 849, 70 Cal.Rptr.3d 466 (Ct. App. 2008) (same).[11] To properly allege a loss of money or property, Plaintiffs must establish either prior possession or a vested legal interest in the money or property lost. *See Walker v. USAA Cas. Ins. Co.*, 474 F. Supp. 2d 1168, 1172 (E.D. Cal. 2007); *see Korea Supply Co. v. Lockheed Martin Corp.*, 29 Cal.4th 1134, 1149, 131 Cal.Rptr.2d 29, 63 P.3d 937 (2003).

Here, Plaintiffs have not so alleged. *See* FAC ¶¶ 53, 67, 81. Instead, Plaintiffs assert that "[o]n information and belief . . . SenoRx's acts and practices . . . have misled and/or deceived and are likely to mislead and/or deceive members of the consuming public with the result that, *inter alia*, they will purchase Contura™ Multi-Lumen Balloons when they would otherwise have purchased MammoSite® Applicators." FAC ¶¶ 66, 79. However, that allegation is not sufficient to confer standing under the UCL of FAL as a matter of law. *See Monolithic Power Sys., Inc. v. O2 Micro Int'l Ltd.*, NO. C 04-2000 CW, C 06-2929 CW, 2007 WL 801886, at *8 (N.D. Cal. Mar. 14, 2007) (claimant may not request illicitly-gained profits unless those funds

[11] Plaintiffs also lack standing to bring UCL and FAL claims for conduct that did not occur in California. *See Norwest Mortgage, Inc. v. Superior Court*, 72 Cal.App.4th 214, 222, 85 Cal.Rptr.2d 18 (1999) (California statutes will normally not be interpreted to "have force or operation beyond the boundaries of the state.").

were previously owned by claimant); *Korea Supply Co.*, 29 Cal.4th at 1151, 131 Cal.Rptr.2d 29, 63 P.3d 937 ("Compensation for a lost business opportunity is a measure of damages and not restitution to the alleged victims.").[12]

2. Plaintiffs Fail To State a Claim for Unfair Competition.

The UCL prohibits "any unlawful, unfair or fraudulent" business practices. *In re Pomona Valley Med. Group*, 476 F.3d 665, 674 (9th Cir. 2007). Because the law is stated in the disjunctive, "it contemplates three distinct categories of unfair competition and a plaintiff must plead the specific rubric under which the proscribed conduct falls." *Philips Med. Capital, LLC v. Med. Insights Diagnostics Ctr., Inc.*, 471 F. Supp. 2d 1035, 1045 (N.D. Cal. 2007). Here, Plaintiffs claim only that "SenoRx's unlawful, unfair, and/or fraudulent business acts and practices described herein constitute unfair competition. . . ." FAC ¶ 57. That is not enough.

First, Plaintiffs fail to allege unlawful business practices. Unlawful business practices means any acts forbidden by law, "be it civil or criminal, federal, state, or municipal, statutory, regulatory, or court-made." *Express, LLC v. Fetish Group, Inc.*, 464 F. Supp. 2d 965, 979 (C.D. Cal. 2006). To allege an unlawful business practice, Plaintiffs must identify the particular statute or regulation SenoRx allegedly violated, and must describe with reasonable particularity the facts supporting the violation. *See Sonoma Foods, Inc. v. Sonoma Cheese Factory, LLC*, NO. C07-00554JSW, 2007 WL 2122638, at *10 (N.D. Cal. Jul. 23, 2007); *Brothers v. Hewlett-Packard Co.*, 2006 WL 3093685, *7 (N.D. Cal. Oct. 31, 2006). Here, even assuming Plaintiffs could predicate their UCL claim on violations of FDCA and FDA regulations, they do not identify those regulations with particularity. *See, e.g.,* FAC ¶ 60 ("SenoRx . . . has no brachytherapy

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[12] Plaintiffs have also failed to allege causation. To show causation, Plaintiffs demonstrate, for each alleged loss of money or property, the loss was occasioned by off-label promotion, and that the prescribing physician based his or her decision to prescribe for an off-label use on an unlawful communication from SenoRx, rather than his or her clinical experience, training and independent medical judgment. *See Ironworkers Local Union No. 68 and Participating Employers Health and Welfare Fund v. Amgen, Inc.*, No. CV 07-5157 PSG (AGRx), 2008 WL 312309, at * 6 (C.D. Cal. Jan. 22, 2008); *United Food & Commercial Workers Cent. PA & Reg'l Health & Welfare Fund v. Amgen, Inc.*, No. CV07-3623PSGAGRX, 2007 WL 4144676, at *6 (C.D. Cal. Nov. 13, 2007); *Painter's Dist. Council No. 30 Health & Welfare Fund v. Amgen, Inc.*, No. CV07-3880PSGAGRX, 2007 WL 4144892, at **5-6 (C.D. Cal. Nov. 13, 2007).

device which is FDA cleared or approved for treatment of superficial excision margins in close proximity to the surface of the skin.").

Second, Plaintiffs fail to allege unfair business practices. The word "unfair," as applied to competitors, means conduct that "threatens an incipient violation of an antitrust law, or violates the policy or spirit of one of those laws because its effects are comparable to or the same as a violation of the law, or otherwise significantly threatens or harms competition." *Cel-Tech Commc'n, Inc. v. Los Angeles Cellular Tel. Co.*, 20 Cal.4th 163, 180, 83 Cal.Rptr.2d 548, 973 P.2d 527 (Cal. 1999); *see* FAC ¶ 51 (implying the Contura and MammoSite devices are competing products). Here, Plaintiffs do not allege any facts that would establish an antitrust injury or violation. Therefore, dismissal is appropriate. *See Kinderstart.com LLC v. Google, Inc.*, NO. C06-2057JFRS, 2007 WL 831806, at *17 (N.D. Cal. Mar. 16, 2007).

Finally, Plaintiffs fail to allege fraudulent business practices. For example, Plaintiffs fail to allege the "who, what, [when], where, and how" of the customer representations on which they rely. *Vess*, 317 F.3d at 1106 (internal quotation marks and citations omitted); FAC ¶ 58. Plaintiffs do not allege when these "customer presentations" were made, how they were made, how frequently they were made, where they were made, to whom they were made, who made them, whether the statements in those presentations were accompanied by other information, whether the representations were given in response to an inquiry from a licensed physician, whether anyone relied on them, or whether the statements were part of an overall scheme to mislead physicians. *See*, *e.g.*, *Cattie v. Wal-Mart Stores, Inc.*, 504 F. Supp. 2d 939, 948 (S.D. Cal. 2007) (plaintiff must both plead and prove reliance on the unfair business practice); *Laster v. T-Mobile USA, Inc.*, 407 F. Supp. 2d 1181, 1194 (S.D. Cal. 2005) (same); *Hall v. Time Inc.*, 158 Cal.App.4th 847, 849, 70 Cal.Rptr.3d 466 (Ct. App. 2008) (same); *see also Neu v. Terminix Int'l., Inc.*, No. C 07-6472 CW, 2008 WL 962096, at *6 (N.D. Cal. Apr. 8, 2008) ("Plaintiff's claims . . . fail because she has not plead with specificity the promotional materials . . .or the

specific representations that constituted the unfair business practices").[13]

Without more, Plaintiffs cannot plausibly claim statements in Exhibit G are false, those statements evidence a fraudulent business practice, they caused Plaintiffs harm, or they are likely to mislead a substantial number of licensed physicians. *See supra* discussion at 6-16; *see also Lavie v. Procter & Gamble Co.*, 105 Cal.App.4th 496, 510, 512, 129 Cal.Rptr.2d 486 (Cal. Ct. App. 2003) (plaintiff must establish a probability that a significant portion of targeted group, viewed from the vantage point of members of that group, will be deceived).

3. Plaintiffs' Fail To State a Claim for False Advertising.

The FAL prohibits a business from disseminating any statement "which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading . . . ." Cal. Bus. & Prof. Code § 17500. Although fraud is not an essential element of a FAL claim, where, as here, Plaintiffs claim sounds in fraud, the particularity requirement of Rule 9(b) of the Federal Rules of Civil Procedure applies. *See Vess*, 317 F.3d at 1105; *see also* FAD ¶ 71 ("SenoRx purposefully and intentionally engaged in unfair, deceptive, untrue, and/or misleading advertising"); FAC ¶ 79 ("SenoRx . . . make[s] such misleading representations with the specific intent that these representations deceive and mislead consumers and potential consumers of brachytherapy products").

In addition, for the same reasons Plaintiffs fail to allege viable Lanham Act and UCL claims, their FAL claim also fails. *See* discussion *supra* at 6-21. [14]

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[13] To the extent Plaintiffs' claims are based on an oral statement made by an employee SenoRx, Plaintiffs have not identified them or alleged any facts to support a finding that the speaker acted as defendant's agent. See *Schwartz v. KPMG LLP*, 476 F.3d 756, 765 (9th Cir.2007) (holding, for purposes of Rule 9(b), where plaintiff alleges defendant is liable under agency theory for false statement of another, plaintiff must allege with particularity facts to support existence of agency relationship). Similarly, if Plaintiffs' theory is that SenoRx has an affirmative duty to disclose information to physicians, Plaintiffs fail to allege, with the requisite particularity, facts to warrant imposition of such a duty. *See Weinstein v. Saturn Corp.*, NO. C-07-0348 MMC, 2007 WL 1342604, at *1 (N.D. Cal. May 8, 2007) ("where fraud claims based on omission, validity of fraud counts depends on allegations that would establish some duty of disclosure on the part of defendant) (citations and internal quotations omitted).

[14] Plaintiffs have also failed to meet the more liberal requirements of Rule 8 of Federal Rule of Civil Procedure. Other than the two statements contained in Exhibit G, Plaintiff refer only to unspecified "customer presentations" and "advertisements." Because Plaintiff does not identify specific statements, this claim does not provide adequate notice to Defendant of the alleged wrongful conduct. *See* Fed. R. Civ. P. 8.

V. CONCLUSION

For the foregoing reasons, Defendant requests its Motion to Dismiss Counts Four, Five and Six of Plaintiffs' First Amended Complaint be granted.

Dated: April 18, 2008

WILSON SONSINI GOODRICH & ROSATI
Professional Corporation

By: s/F.T. Alexandra Mahaney
F.T. Alexandra Mahaney
amahaney@wsgr.com

Attorneys for Defendant and Counterclaimant
SENORX, INC.

CERTIFICATE OF SERVICE
U.S. District Court, Northern District of California,
Hologic, Inc. et al. v. SenoRx, Inc.
Case No. C-08-0133 RMW (RS)

I, Kirsten Blue, declare:

I am and was at the time of the service mentioned in this declaration, employed in the County of San Diego, California. I am over the age of 18 years and not a party to the within action. My business address is 12235 El Camino Real, Ste. 200, San Diego, CA, 92130.

On April 18, 2008, I served a copy(ies) of the following document(s):

DEFENDANT SENORX, INC.'S NOTICE OF MOTION AND MOTION TO DISMISS AND MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF (REDACTED VERSION)

on the parties to this action by placing them in a sealed envelope(s) addressed as follows:

Henry C. Su (suh@howrey.com) Katharine L. Altemus (altemusk@howrey.com) HOWREY LLP 1950 University Avenue, 4th Floor East Palo Alto, CA 94303 Telephone: (650) 798-3500 Facsimile: (650) 798-3600	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP
Matthew Wolf (wolfm@howrey.com) Marc Cohn (cohnm@howrey.com) HOWREY LLP 1229 Pennsylvania Avenue, NW Washington, DC 20004 Telephone: (202) 783-0800 Facsimile: (202) 383-6610	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP

☒ (BY MAIL) I placed the sealed envelope(s) for collection and mailing by following the ordinary business practices of Wilson Sonsini Goodrich & Rosati, 12235 El Camino Real, Ste. 200, San Diego, CA. I am readily familiar with WSGR's practice for collecting and processing of correspondence for mailing with the United States Postal Service, said practice being that, in the ordinary course of business, correspondence with postage fully prepaid is deposited with the United States Postal Service the same day as it is placed for collection.

☒ (BY ELECTRONIC MAIL) I caused such document(s) to be sent via electronic mail (email) to the above listed names and email addresses.

☐ (BY PERSONAL SERVICE) I caused to be delivered by hand to the addressee(s) noted above. I delivered to an authorized courier or driver to be delivered on the same date. A proof of service signed by the authorized courier will be filed with the court upon request.

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overnight delivery, said practice being that, in the ordinary course of business, correspondence for overnight delivery is deposited with delivery fees paid or provided for at the carrier's express service offices for next-day delivery the same day as the correspondence is placed for collection.

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☒ (BY CM/ECF) I caused such document(s) to be sent via electronic mail through the Case Management/Electronic Case File system with the U.S. District Court for the Northern District of California.

I declare under penalty of perjury under the laws of the United States that the above is true and correct, and that this declaration was executed on April 18, 2008.

Kirsten Blue

F.T. Alexandra Mahaney, State Bar No. 125984
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Bruce R. Genderson (admitted *pro hac vice*)
Aaron P. Maurer (admitted *pro hac vice*)
Rachel Shanahan Rodman (admitted *pro hac vice*)
Adam D. Harber (admitted *pro hac vice*)
WILLIAMS & CONNOLLY LLP
725 Twelfth St. NW
Washington, DC 20005
Telephone: (202) 434-5000
Facsimile: (202) 434-5029

Attorneys for Defendant and Counterclaimant
SENORX, INC.

IN THE UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORPORATION and HOLOGIC L.P.,

Plaintiffs,

v.

SENORX, INC.,

Defendant.

SENORX, INC.,

Counterclaimant,

v.

HOLOGIC, INC., CYTYC CORPORATION and HOLOGIC L.P.,

Counterdefendants.

Case No. 08-CV-0133 RMW

DECLARATION OF AARON P. MAURER IN SUPPORT OF DEFENDANT SENORX, INC.'S MOTION TO DISMISS

Date: June 6, 2008
Time: 9:00 a.m.
Judge: Hon. Ronald M. Whyte
Trial Date: Not yet set

I, Aaron P. Maurer, declare that I am a Partner at the law firm of Williams & Connolly LLP, and outside counsel for Defendant and Counterclaimant SenoRx, Inc. in the above-captioned matter. The following declaration is based on my personal knowledge, and if called to testify I could and would competently testify as to the matters set forth herein.

1. Attached hereto as Exhibit 1 is a true and correct copy of a document produced in this litigation by Defendant, bates numbered SRX-HOL00005563-5565, dated March 14, 2008 and submitted under seal.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: April 18, 2008

Aaron Maurer /BSR
Aaron P. Maurer

CERTIFICATE OF SERVICE
U.S. District Court, Northern District of California,
Hologic, Inc. et al. v. SenoRx, Inc.
Case No. C-08-0133 RMW (RS)

I, Kirsten Blue, declare:

I am and was at the time of the service mentioned in this declaration, employed in the County of San Diego, California. I am over the age of 18 years and not a party to the within action. My business address is 12235 El Camino Real, Ste. 200, San Diego, CA, 92130.

On April 18, 2008, I served a copy(ies) of the following document(s):

DECLARATION OF AARON P. MAURER IN SUPPORT OF DEFENDANT SENORX, INC.'S MOTION TO DISMISS

on the parties to this action by placing them in a sealed envelope(s) addressed as follows:

Henry C. Su (suh@howrey.com) Katharine L. Altemus (altemusk@howrey.com) HOWREY LLP 1950 University Avenue, 4th Floor East Palo Alto, CA 94303 Telephone: (650) 798-3500 Facsimile: (650) 798-3600	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP
Matthew Wolf (wolfm@howrey.com) Marc Cohn (cohnm@howrey.com) HOWREY LLP 1229 Pennsylvania Avenue, NW Washington, DC 20004 Telephone: (202) 783-0800 Facsimile: (202) 383-6610	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP

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I declare under penalty of perjury under the laws of the United States that the above is true and correct, and that this declaration was executed on April 18, 2008.

Kirsten Blue

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTIC CORPORATION and HOLOGIC L.P.,

Plaintiffs,

v.

SENORX, INC.,

Defendant.

AND RELATED COUNTERCLAIMS

CASE NO.: C08-0133 RMW (RS)

[PROPOSED] ORDER GRANTING DEFENDANT SENORX, INC.'S MOTION TO DISMISS

The Court, having considered the papers in support of and in opposition to Defendant SenoRx, Inc.'s Motion to Dismiss, and being fully advised in the proceedings, and for good cause appearing, hereby GRANTS the Motion in its entirety.

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that the Fourth, Fifth and Sixth Causes of Action in the Amended Complaint are DISMISSED with prejudice.

Dated: _____, 2008

By: _____
Honorable Ronald M. Whyte
United States District Court Judge

CERTIFICATE OF SERVICE
U.S. District Court, Northern District of California,
Hologic, Inc. et al. v. SenoRx, Inc.
Case No. C-08-0133 RMW (RS)

I, Kirsten Blue, declare:

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I declare under penalty of perjury under the laws of the United States that the above is true and correct, and that this declaration was executed on April 18, 2008.

Kirsten Blue

F.T. Alexandra Mahaney, State Bar No. 125984
Natalie J. Morgan, State Bar No. 211143
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Attorneys for Defendant and Counterclaimant
SENORX, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORPORATION and HOLOGIC L.P., Plaintiffs, v. SENORX, INC., Defendant.	Case No. C-08-0133 RMW (RS) **DEFENDANT AND COUNTERCLAIMANT SENORX, INC.'S NOTICE OF MANUAL FILING** Date: June 6, 2008 Time: 9:00 a.m. Ct. Rm: Courtroom 6, Fourth Floor Judge: Hon. Ronald M. Whyte
SENORX, INC., Counterclaimant, v. HOLOGIC, INC., CYTYC CORPORATION and HOLOGIC L.P., Counterdefendants.	

Regarding: **Exhibit 1 to the Declaration of Aaron P. Maurer in Support of Defendant SenoRx, Inc.'s Motion to Dismiss and confidential version of Defendant SenoRx, Inc's Memorandum of Points and Authorities in Support of Motion to Dismiss.**

This filing is in paper or physical form only, and is being maintained in the case file in the Clerk's office. If you are a participant in this case, this filing will be served in hard-copy shortly. For information on retrieving this filing directly from the court, please see the court's main web site at http://www.cand.uscourts.gov under Frequently Asked Questions (FAQ).

This filing was not efiled for the following reason(s):

[X] Item(s) Under Seal

Dated: April 18, 2008

Respectfully submitted,

By: s/F.T. Alexandra Mahaney

F.T. Alexandra Mahaney, State Bar No. 125984
WILSON SONSINI GOODRICH & ROSATI
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Attorneys for Defendant and Counterclaimant
SENORX, INC.

CERTIFICATE OF SERVICE
U.S. District Court, Northern District of California,
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Case No. C-08-0133 RMW (RS)

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Kirsten Blue