UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

PHOTOMEDEX, INC., Plaintiff, vs. RA MEDICAL SYSTEMS INC. AND DEAN STEWART IRWIN, Defendants.	CASE NO. 04CV24 JLS (CAB) **ORDER GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

Presently before the Court are Defendants' motion for summary judgment [Doc. No. 118], Plaintiff's opposition to the motion for summary judgment [Doc. No. 123], and Defendants' reply [Doc. No. 124.] For the following reasons, this Court **GRANTS** Defendants' motion.

BACKGROUND

A. Parties' History

Plaintiff Photomedex markets an excimer laser to medical professionals, primarily dermatologists, for the treatment of psoriasis and vitiligo. Defendant Dean Irwin formerly worked for Photomedex as its Vice President of Research and Development. [See Irwin Decla. ¶ 9.] Mr. Irwin resigned from that position in 2002 and incorporated RA Medical, Inc. in early 2003. [Id.] On March 13, 2003, RA Medical entered into a licensing agreement with another company, Surgilight, for the rights to market, sell, and promote Surgilight's laser that was already cleared by

the Food & Drug Administration ("FDA") to treat psoriasis and vitiligo. [Def.'s Motion, Exhibit 35.]

Soon after the licensing agreement, Mr. Irwin and members of RA Medical appeared at a trade show held by the American Academy of Dermatology ("AAD Show") and offered written materials to attendees advertising a competing excimer laser known as the Pharos Excimer Laser ("Pharos"). [See Leonard Decla., Exhibit A.] Defendant Irwin handed out a brochure that stated the Pharos was "FDA Approved for Psoriasis and Vitiligo" and that he was an inventor. [Id.]

Plaintiff alleges that the Pharos laser Defendants were marketing was vastly different than the Surgilight laser that was FDA approved. [Pl.'s Opp at 12-14.] Therefore, Plaintiff argues Defendants were essentially marketing a laser as FDA approved when it was not. [Id.] As a result, Plaintiff contends that Defendants' representations about the Pharos and other statements disseminated through brochures at the AAD Show and other trade shows were false and misleading. [See Compl. ¶ 17.] Plaintiff further states that these misrepresentations helped Defendants capture sales that Plaintiff would have received. Id. Consequently, Plaintiff is seeking damages for lost profits and unjust enrichment and also an injunction enjoining Defendants from disseminating such misleading statements. [Id.] Specifically, Plaintiff is suing for alleged violations of the Lanham Act, California Business and Profession Code ("B&P Code") Section 17500, and B&P Code Section 17200. [See Compl. ¶¶ 7-27.]

In response, Defendants argue: (1) they marketed a laser that was FDA approved and simply made design changes to it; (2) the FDA related claims should remain in the exclusive jurisdiction of the FDA; (3) the projected release date was an estimate and is therefore non-actionable; and (4) Mr. Irwin properly represented himself as an "inventor," and, in the alternative, the issue is a matter of opinion and is non-actionable.

LEGAL STANDARD

Under Rule 56(c), summary judgment is proper when the pleadings and discovery, read in the light most favorable to the nonmoving party, demonstrate that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Armstrong

v. Burlington N. R.R. Co., 139 F.3d 1277, 1278 (9th Cir. 1998) (quoting 20th Century Ins. Co. v. Liberty Mut. Ins. Co., 965 F.2d 747, 750 (9th Cir. 1992)); see also Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A dispute is "genuine" when "the evidence presented is such that a jury applying [the appropriate] evidentiary standard could reasonably find for either the plaintiff or the defendant." Anderson, 477 U.S. at 255.

Even where some facts are disputed, summary judgment is still appropriate "[i]f the evidence is merely colorable, or is not significantly probative." Anderson, 477 U.S. at 249-50. No genuine issue for trial exists if "the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party." Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986).

ANALYSIS

A. Plaintiff Lacks Standing Because the FDA Has Exclusive Jurisdiction Over Determining Whether Defendants Improperly Branded Their Product as "FDA Approved"

1. Background Law

The Food, Drug, and Cosmetic Act ("FDCA") gives the FDA comprehensive regulatory authority over medical devices. 21 U.S.C. §§ 360c-3601 (2007); Fender v. Medtronic, Inc., 887 F.Supp. 1326, 1329 (E.D. Cal. 1995). Section 337(a) of the FDCA provides that "all proceedings for the enforcement, or to restrain violations of [the Act] shall be by and in the name of the United States." Courts have interpreted this provision of the FDCA to mean that no private right of action exists to address violations of the FDCA and that the right to enforce the Act's provisions lies within the federal government's domain, by way of either the FDA or the Department of Justice. See Gile v. Optical Radiation Corp., 22 F.3d 540, 544 (3d Cir. 1994), cert. denied, 115 S. Ct. 429 (1994) (citing Pacific Trading Co. v. Wilson & Co., Inc., 547 F.2d 367, 370 (7th Cir. 1976) ("violations of the FDCA do not create private rights of action")); Milan Laboratories, Inc. v. Matcher, 7 F.3d 1130, 1139 (4th Cir. 1993), cert. denied, 114 S. Ct. 1307 (1994) (citing the same principle); Ginochio v. Surgikos, Inc., 864 F. Supp. 948, 956 (N.D. Cal. 1994) (citing various courts that have held that "there is no private cause of action for violation of the Food, Drug, and

Cosmetic Act").

For example, in Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 343 (2001), the Supreme Court held that such state-law "fraud on the FDA" claims are pre-empted by the FDCA as amended by the Medical Device Amendments ("MDA"), 21 U.S.C. § 301. Furthermore, other courts have also been reluctant to entertain related federal Lanham Act claims based on a similar rationale. In Summit Tech. V. High Line Medical Instruments Co., 922 F. Supp. 299, 305 (C.D. Cal. 1996), plaintiff sued its business competitor under the Lanham Act because it failed to disclose that its laser systems did not receive FDA approval. The court dismissed the action and stated that allowing it to proceed would "usurp the FDA's discretionary role in the application and interpretation of its regulations. . . As such this would use the Lanham Act as a vehicle for enforcing the requirements of the FDCA." Id.; see also Sandoz Pharmaceuticals v. Richardson-Vicks, Inc., 902 F.2d 222, 231 (3d Cir. 1990) ("[W]hat the FD & C Act . . . [does] not create directly, the Lanham Act does not create indirectly[.]").

However, some courts have acknowledged that a plaintiff could present a Lanham Act claim if the allegations involved an affirmative misrepresentation of a fact, such as stating that a product was FDA approved when it was not. Summit, 922 F. Supp. at 307; Milan, 7 F.3d at 1139. Those courts have been willing to hear such claims because that determination would not require the court to interpret the application of FDA regulations. Id.

2. Application to Instant Action

In this action, Plaintiff attempts to persuade this Court that its "fraud on the FDA" claim fits within this narrow opening. Plaintiff argues its claims should not be dismissed because it is alleging that Defendants represented the Pharos laser was FDA approved when it allegedly was not. This Court disagrees with Plaintiff's characterization of its claim.

A timeline of the relevant dates of market clearance clarifies this issue. Surgilight obtained market clearance for their "EX-308" laser for the treatment of psoriasis on July 18, 2000. [See Reply, Exhibit 1.] On March 29, 2002, Surgilight obtained further market clearance for the EX-308 Laser for the treatment of vitiligo and psoriasis. [See Reply Exhibit 2.] On March 13, 2003, RA Medical entered into a licensing agreement with Surgilight for the rights to Surgilight's

previously cleared laser. [See Def.'s Motion, Exhibit 35.] After the licensing agreement was made, Defendants made various changes to the licensed technology. [Irwin Decla. at ¶ 10.; Pl.'s Opp. Exhibit E., King Depo., 163:24-164:1, 168:9-168:10.] Plaintiff now alleges that Defendants made misrepresentations about the laser after entering into this license agreement. [Pl's Opp. at 13.]

It appears that on September 27, 2006, RA Medical submitted a new "510(k)" to the FDA to obtain further market clearance for the EX-308 to treat atopic detmatitis and leukoderma.[1] [See Reply, Exhibit 4.] On January 30, 2007, the FDA warned the Defendants not to market the laser for the additional purposes identified in the new 510(k). [See Reply, Exhibit 5.] Finally, on April 3, 2007, the FDA granted further market clearance for the additional treatments of atopic dermatitis and leukoderma.

On the basis of its experts, Plaintiff asserts that there was a major difference between the licensed laser and the marketed laser and that Plaintiffs should have gone back to the FDA for further market clearance.[2] [Pl.'s Opp. at 8-10.] From this belief, Plaintiff claims that Defendants were improperly marketing a laser as FDA approved when it was not. [Pl.'s Opp. at 6-14.] However, Plaintiff's actual argument before this Court, as shown by its experts' declarations, relates to whether the design changes made by Defendants to the Surgilight laser required Defendants to file additional documents with the FDA to obtain further FDA pre-market clearance. [Id. at 8-10.] This is far different than the question of whether Defendants affirmatively misrepresented that the laser was FDA approved when it was not. It is the former that requires the FDA's scientific expertise and application of FDA regulations, and therefore, it is the former that is a question lying outside of this Court's jurisdiction. See Summit, 922 F.Supp. at 305.

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[1] Put simply, the FDA market clearance procedures instruct manufacturers, in their sole discretion, to submit a new 510(k) document to the FDA when a change, or the sum of incremental changes, exceeds the regulations' threshold, e.g., could significantly affect the safety or effectiveness of the device. See Part 807, C.F.R. Sections 807.81 and 807.100.

[2] Plaintiff also provides the Court evidence of a conversation between one of its experts and an FDA official, Larry Spears. [Pl.'s Opp. at 11.] Plaintiff offers the evidence to show that Defendants were required to file a new 510(k) because of changes made to the laser. [Id.] However, as noted by Defendants in their objection, the conversation is hearsay evidence, inadmissable, and will not be considered by this Court on review of the summary judgment motion. See Orr v. Bank of America, NT & SA, 285 F.3d 764, 773-79 (9th Cir. 2002).

3. FDA Involvement with Defendants

The aforementioned case law and statutes demonstrate that this Court does not have jurisdiction over Plaintiff's actual claim; however, the fact that the FDA has already reviewed this precise issue further demonstrates that this cause of action should remain in the province of the FDA.

Plaintiff's representatives sent a series of letters to the FDA to encourage them to require Defendants to submit a new 510(k) seeking further FDA clearance. [Def's Motion, Exhibits, 1, 2, 3, 4, 5, 6, 7, 8 & 9.] Upon receiving those letters, the FDA inspected Defendants' product and facilities in October of 2005, and issued its Establishment Inspection Report ("EIR"). The FDA took no action against Defendants, issued minor deficiencies, and permitted the continued marketing and sale of its product under Surgilight's previously filed, cleared, and licensed 510(k)s. [Def.'s Motion Exhibit 20.] In its report, the FDA stated: "During the inspection, [it] investigated the statements made in the consumer complaints [and] many of the statements were unfounded or not representative of the firm's current operations." Id. Further, in the EIR, the inspector stated that she discussed the issue of whether to submit a new 510(k) with Defendant Irwin. She noted: "because of the complexity in explaining the differences between the Pharos EX-308 and the Surgilight EX-308," she asked Mr. Irwin to submit a written explanation to the FDA. Id. Defendant Irwin submitted the explanation to the FDA and the FDA did not take any action in response. Id.[3]

In sum, whether or not the regulatory agencies permitted Defendants to continue to manufacture and market their product, Plaintiff has no standing to assert its "fraud on the FDA claims." Furthermore, regardless of what Plaintiff and their experts believe ought to have been done to obtain further clearance, the issue lies in the province of the FDA. Therefore, this Court

[3] Subsequently, Plaintiff's representatives then corresponded mutiple times with the California Department of Health Services ("CDHS") requesting action. [See Def.'s Motion, Exhibits 10-16.] The CDHS concluded that RA Medical was in good standing with the FDA. [See Def.'s Motion, Exhibit 40, Moynier Depo., 68:4, 70:23.]

DISMISSES Plaintiff's "fraud on the FDA" claims for Plaintiff's lack of standing.[4]

B. Defendants' Statement Regarding the Release Date of Defendants' Laser is a Non-Actionable Forward Looking Statement

In Bayview Hunters Point Community Advocates v. Metropolitan Trans. Comm., 366 F.3d 692, 698 (9th Cir. 2004) (citations and quotations omitted), the Ninth Circuit stated that "predictions as to future events are ordinarily non-actionable expressions of opinion under basic principles of the tort of fraudulent misrepresentation."

Defendants simply made an estimate as to their product's release date. Plaintiff's Chief Technical Officer understood that Defendants were making an estimate as to when the product would be available. [See Def.'s Motion, Exhibit 41, Depo. Jeffrey LaVatter Depo., 172: 11-13.] Moreover, in a Surgilight public press release regarding the licensure of the laser to RA Medical, Defendants stated that the product was not yet available. [See Reply, Exhibit 7.] Plaintiff offers no evidence of malfeasance surrounding Defendants' estimation and offers no case law indicating why this Court should depart from the reasoning of Bayview. Therefore, this Court finds that claims related to the release date estimates are non-actionable.

C. Defendant Irwin's Statement that He Was An Inventor is a Matter of Opinion and Was Not Misleading

Plaintiff argues that Defendant Irwin misrepresented himself as an "inventor" of the first

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[4] This Court notes Plaintiff's argument that in the January 2007 letter, the FDA was not warning Defendants about marketing the product for additional uses, but instead, was warning Defendants not to market their product at all. From reading the FDA letters, this Court cannot definitively determine that Plaintiff is incorrect. However, Plaintiff's argument itself reveals that it is asking this Court to enter the field of interpreting unclear FDA correspondence and, in essence, the FDA's application of its own regulations. As stated, this an area outside of this Court's jurisdiction. See Summit, 922 F. Supp. at 305.

Moreover, after nearly four years of FDA involvement with this issue, the strongest reprimand from the FDA against Defendants came from this January 2007 letter that stated the FDA "has information that suggests that your firm is manufacturing and marketing the EX-308 Excimer Laser . . . without market clearance or approval . . ." [Def.'s Reply, Exhibit 4.] Four months later, in April of 2007, the FDA determined Defendants were clear to market the device. [Def.'s Reply, Exhibit 4.] Thus, overall, the law indicates this matter should fall within the FDA's province and the facts demonstrate that the matter is in the FDA's province. Therefore, this Court finds the matter should remain there.

FDA approved laser system for the treatment of psoriasis and vitiligo. Defendants argue that Mr. Irwin was the inventor, and in the alternative, that the issue is a matter of opinion.

There may not be a precise guideline of who can justly call themself an "inventor." However, the evidence shows that Mr. Irwin's participation in the development of the laser brings him, at a minimum, fairly close to meeting Plaintiff's own definitions. [Def.'s Motion, Exhibit 42, Levatter Depo., 38:13-18, 34:2-23; Def.'s Motion, Exhibit 39, McGrath Depo., 22:19-21.] More importantly, the evidence shows that calling himself an "inventor" would not constitute misleading or fraudulent behavior under the Lanham Act or the relevant state statutes raised in this action.

Plaintiff recognizes many individuals were involved in the invention, and that Defendant Irwin was part of the team who built the laser. [Def.'s Motion; Exhibit 39, McGrath Depo., 28:6-11.] Also, while serving as the Vice-President of Research and Development at Photomedex in 2001, Mr. Irwin took part in a television broadcast that introduced the laser at issue. [Def.'s Motion, Exhibit 39; McGrath Depo., 25:19-22; Irwin Decla. ¶ 12.] During the television interview, Irwin was identified as the "Photomedex engineer who developed, tested and perfected the psoriasis-treating laser system." [Def.'s Motion, Exhibit 43, Irwin Decla. ¶ 12.] In the same interview, the Chief Operating Officer stated that Photomedex was the "first to get FDA approval for laser treatment of psoriasis" and later stated "it's really special to be on the forefront of a product line that is, that nobody else has in a, in a technology that is not available in any other way." [See Id.] Following the broadcast, Plaintiff's representatives took copies of the tapes and broadcasted them at trade shows puffing the company's product. [Def.'s Motion, Exhibit 39, McGrath Depo., 26:5-7.]

In addition, Mr. Irwin has an ethical and contractual obligation to sign all patents worked on while at Photomedex. [Irwin Decla. ¶ 14.] Accordingly, as late as 2007, Plaintiff sent Mr. Irwin patent documents that identified him as an inventor of the laser at issue. [Irwin Decla. ¶ 14.; Def.'s Motion, Exhibit 44.] Pursuant to his obligation, Mr. Irwin signed the patent documents and Plaintiff has since obtained the patent in Mr. Irwin's name as an inventor. [Def.'s Motion, Exhibit 44, United States Patent Application.]

In sum, it appears Defendant Irwin was significantly involved with the development of the

laser at its infancy and his name is listed as an inventor on the patent itself. Therefore, this Court finds Defendant Irwin did not misrepresent himself when stating he was an inventor.

CONCLUSION

To conclude, Plaintiff does not have standing on its "fraud on the FDA" claim. Furthermore, Defendants' release date estimate and use of the term "inventor" are non-actionable issues. Thus, this Court **GRANTS** Defendants' motion for summary judgment.

The Clerk of the Court **SHALL ENTER** judgment for the Defendants. This order hereby **CONCLUDES** the litigation in this case.

IT IS SO ORDERED.

DATED: October 29, 2007

Janis L. Sammartino
Honorable Janis L. Sammartino
United States District Judge