FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

PHOTOMEDEX, INC., a Delaware corporation, *Plaintiff-Appellant,* v. DEAN STEWART IRWIN, an individual; RA MEDICAL SYSTEMS, INC., a California corporation, *Defendants-Appellees.*	No. 07-56672 D.C. No. CV-04-00024-JLS OPINION

Appeal from the United States District Court
for the Southern District of California
Janis L. Sammartino, District Judge, Presiding

Argued and Submitted
June 4, 2009—Pasadena, California

Filed April 14, 2010

Before: William A. Fletcher, Richard R. Clifton and
Milan D. Smith, Jr., Circuit Judges.

Opinion by Judge Clifton

COUNSEL

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OPINION

CLIFTON, Circuit Judge:

Plaintiff PhotoMedex, Inc. appeals the district court's grant of summary judgment in favor of Defendants Dean Stewart Irwin and Ra Medical Systems, Inc. on Lanham Act claims for misleading advertising and on California state law claims for false advertising and unfair competition. These claims are based on allegations of three separate misrepresentations made by Defendants regarding: (1) clearance by the Food and Drug Administration (FDA) to market their laser device, (2) the anticipated date their laser would be available for purchase, and (3) Irwin's role as inventor of PhotoMedex's laser device.

The first alleged misrepresentation requires us to address the question of whether a medical device manufacturer who is not permitted to bring a private action to enforce the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, may nevertheless maintain a suit under the Lanham Act based on a claim that a competitor violated the FDCA by misrepresenting that its product had received FDA clearance, when the FDA declined to make a finding that there was no valid clearance or to bring an enforcement action itself. Under the particular circumstances of this case, where the FDA permits Defendants to determine in the first instance whether their laser device was covered by clearance previously given to a similar device and to market their device without an affirmative statement of approval by the FDA, we conclude that the claim by PhotoMedex may not proceed.

We conclude, however, that claims based on the other two alleged misrepresentations are potentially viable, including claims alleging a false projection of when a product would be available on the market. Though a forecast of future events may ordinarily be a statement of opinion upon which such claims cannot be based, we conclude that such a statement may be actionable if the speaker knew at the time the statement was made that it was false or did not have a good faith belief in the truth of what was said. The commercial depiction of Irwin as inventor of Photomedex's laser is also actionable because it may misrepresent his actual contribution.

We affirm the summary judgment for the claim based on alleged misrepresentations regarding FDA clearance but vacate summary judgment on the claims based on alleged misrepresentations regarding the release date for Ra Medical's laser and Irwin's role as the inventor of PhotoMedex's laser.

I. Background

PhotoMedex directly competes with Ra Medical in the production and sale of lasers for use in dermatological treatments. These dermatological lasers are regulated by the FDA and must pass what is known as the "510(k)" clearance process, described below, before being placed on the market. PhotoMedex's product is the "XTRAC Excimer Laser System" (XTRAC), the first excimer laser the FDA cleared for the treatment of the skin disorders psoriasis and vitiligo.

Irwin served on the development team for the XTRAC system during his employment with PhotoMedex from February 1998 to July 2002. Following his departure from PhotoMedex, Irwin co-founded Ra Medical in September 2002.

Ra Medical entered into a licensing agreement for a competing laser product with SurgiLight, Inc. on March 13, 2003. SurgiLight had received FDA 510(k) clearance in March 2002

for its "EX-308" excimer laser for the treatment of psoriasis and vitiligo, though at the time of the agreement it had not actually manufactured or marketed the cleared laser. In exchange for royalties, SurgiLight gave Ra Medical the "exclusive manufacturing rights and exclusive marketing rights for [the FDA-cleared EX-308 device], including any derivative devices, substantially conforming to the specifications[,] as well as the exclusive right to use its mark EX-308 on devices [Ra Medical] intends to manufacture and market."

After securing the license from SurgiLight, Irwin appeared on Ra Medical's behalf at a trade show held by the American Academy of Dermatology in March 2003. At the show, Defendants distributed a brochure which proclaimed that Ra Medical's "Pharos EX-308 Excimer Laser" (Pharos) was "FDA Approved for Psoriasis & Vitiligo." This brochure also described Irwin as "inventor of the first FDA approved excimer laser for phototherapy," i.e., PhotoMedex's XTRAC laser. Defendants' subsequent marketing materials made similar promotional claims.

Word spread that the Pharos would be available for purchase within a few months. The record includes evidence that a person attending the trade show heard that the Pharos was scheduled for sale in August 2003. SurgiLight issued a press release, also in March 2003, announcing that "Ra Medical anticipates the introduction of its PHAROS EX-308, Excimer laser system for treatment by dermatologists of psoriasis and vitiligo (pigmentation loss) this summer." Defendants did not actually ship the first Pharos laser until September 2004, more than a year after the projected introduction date. The Pharos laser differed in some respects from SurgiLight's already-cleared EX-308 laser.

PhotoMedex filed the present action against Defendants, asserting violations of the Lanham Act and California laws prohibiting untrue and misleading advertising and unfair competition. The district court granted summary judgment in

favor of Defendants on each of these claims. The court held PhotoMedex lacked standing to challenge whether Defendants improperly promoted their laser as "FDA approved" because the FDA retains exclusive jurisdiction over FDCA enforcement. The court determined Defendants' predicted release date for its laser was a non-actionable forward-looking statement. Defendants' assertion that Irwin invented PhotoMedex's laser was held to be a matter of opinion and not misleading. PhotoMedex timely appealed.

II. Discussion

We review the district court's grant of summary judgment as well as its statutory interpretations de novo. *United States v. Able Time, Inc.*, 545 F.3d 824, 828 (9th Cir. 2008). We must determine whether, viewing the evidence in the light most favorable to PhotoMedex as the nonmoving party, there are any genuine issues of material fact and whether the district court correctly applied the relevant substantive law. *McClung v. City of Sumner*, 548 F.3d 1219, 1223 (9th Cir. 2008).

[1] Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B), explicitly furnishes a private right of action "against persons who make false and deceptive statements in a commercial advertisement about their . . . product." *Jarrow Formulas, Inc. v. Nutrition Now, Inc.*, 304 F.3d 829, 834-35 (9th Cir. 2002).[1] "Under the Lanham Act, a prima facie case

[1]The statute states, in relevant part:

> (1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any . . . false or misleading description of fact, or false or misleading representation of fact, which —
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> . . .
>
> (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a).

requires a showing that . . . the defendant made a false statement either about the plaintiff's or its own product . . . ." *Newcal Indus., Inc. v. Ikon Office Solution*, 513 F.3d 1038, 1052 (9th Cir. 2008) (internal quotation marks omitted).

A. Claims Regarding FDA Clearance

[2] The FDCA, as amended by the Medical Device Amendments of 1976 (MDA), 90 Stat. 539, (codified at 21 U.S.C. § 301 *et seq.*), imposes a comprehensive set of requirements upon medical devices. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001). The FDA is charged with investigating potential violations. 21 U.S.C. § 372. The FDCA provides the FDA with a number of enforcement remedies that may be sought. *Buckman*, 531 U.S. at 349; *Heckler v. Chaney*, 470 U.S. 821, 835 (1985); *see, e.g.*, 21 U.S.C. §§ 332 (injunction proceedings), 333 (civil and criminal penalties), 334 (seizure). Citizens may petition the FDA to take administrative action. 21 C.F.R. §§ 10.25(a), 10.30.

[3] Section 337(a) of the FDCA bars private enforcement of the statute, stating that "all such proceedings for the enforcement, or to restrain violations, of this [Act] shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Supreme Court has observed that 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." *Buckman*, 531 U.S. at 349 n.4.

[4] The Supreme Court made clear in *Buckman* that this section also limits the ability of a private plaintiff to pursue claims under state law theories where such claims collide with the exclusive enforcement power of the federal government. *Id*. at 343, 349-50, 353 (holding that a state tort claim based on alleged fraudulent representations made by a medical device manufacturer in the course of seeking market approval from the FDA "would exert an extraneous pull on the scheme

established by Congress, and it is therefore pre-empted by that scheme").

[5] Our court has not previously spoken to the question of whether the FDCA limits claims under the Lanham Act.[2] We conclude, in the circumstances of this case, that it does. Because the FDCA forbids private rights of action under that statute, a private action brought under the Lanham Act may not be pursued when, as here, the claim would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation.

To be clear, we do not suggest that the Lanham Act can never support private party claims involving FDA approval or clearance of drugs or medical devices. That is not the case. If, for example, 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. But this case does not fit that pattern.

[2]We have recognized that a Lanham Act claim might be barred as inconsistent with another federal statute. In *Sybersound Records, Inc. v. UAV Corp.*, 517 F.3d 1137 (9th Cir. 2008), we held that "a party lacking standing to bring a copyright infringement suit under the Copyright Act, but who complains of competitive injury stemming from acts of alleged infringement, may [not] bring a Lanham Act claim . . . whose successful prosecution would require the litigation of the underlying infringement claim." *Id.* at 1141. In that case, the plaintiff, a karaoke record producer, sued competitors for purportedly misrepresenting to consumers that they had obtained licenses from every copyright holder of the songs on their records. We declined to construe the Lanham Act "to cover misrepresentations about copyright licensing status" because doing so "would allow competitors engaged in the distribution of copyrightable materials to litigate the underlying copyright infringement when they have no standing to do so because they are nonexclusive licensees or third party strangers under copyright law." *Id.* at 1144.

Permitting PhotoMedex's Lanham Act claim to proceed in the circumstances of this case would intrude on the exclusive government enforcement authority established under the FDCA. Explaining why PhotoMedex may not pursue its claim in this instance requires some understanding of how the FDCA, in conjunction with the MDA, operates in the context of this kind of medical device.

[6] "The MDA separates devices into three categories: Class I devices are those that present no unreasonable risk of illness or injury and therefore require only general manufacturing controls; Class II devices are those possessing a greater potential dangerousness and thus warranting more stringent controls; Class III devices present a potential unreasonable risk of illness or injury and therefore incur the FDA's strictest regulation." *Buckman*, 531 U.S. at 344 (internal quotation marks and alteration omitted); *see also Mendes v. Medtronic, Inc.*, 18 F.3d 13, 14 (1st Cir. 1994) ("The MDA reflects Congress's balancing the need for regulation to protect public health against its interest in allowing new and improved devices to be marketed expeditiously without the costs attributable to an excess of regulation."). The dermatological lasers involved in this case are all Class II devices. *See* 21 C.F.R. § 878.4810 (issuing a Class II designation for these types of lasers).

[7] Unlike a manufacturer of a Class III device, which must go through the "rigorous" process of obtaining "premarket approval" from the FDA before being allowed to market its device, a manufacturer of a Class II device need only submit a "premarket notification" to the FDA, in accordance with the less burdensome "510(k) process." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477-79 (1996) (contrasting the two procedures); *see* 21 U.S.C. § 360c(a)(1)(B), (C). Under the 510(k) process, if the Class II device is deemed "substantially equivalent" to a pre-existing device with prior clearance, "it can be marketed without further regulatory analysis." *Medtronic*, 518 U.S. at 478; *see also* 21 U.S.C. § 360(k); 21 C.F.R.

§ 807.100. In other words, that device receives "510(k) clearance" and can be put on the market.[3]

FDA regulations provide that a manufacturer who has successfully navigated the 510(k) process for a device must make a new 510(k) submission whenever the device "is about to be significantly changed or modified in design, components, method of manufacture, or intended use." 21 C.F.R. § 807.81(a)(3).[4] An FDA guideline document makes clear that responsibility is placed on the manufacturer to decide whether device changes necessitate a new 510(k) submission. FDA, *Deciding When to Submit a 510(k) for a Change to an Existing Device*, 1997 WL 33793777 (Jan. 10, 1997). That document explains:

> When making the decision on whether to submit a 510(k), the manufacturer's basis for comparison of any changed device should be the device described by the cleared 510(k) . . . . That is, manufacturers may make a number of changes without having to submit a 510(k), but each time they make a change,

[3]Unlike premarket approval, 510(k) clearance "does not in any way denote official approval of the device." 21 C.F.R. § 807.97. PhotoMedex does not argue that Defendants' "FDA approved" statement is in itself false or misleading on the ground that the FDA does not "approve" Class II devices in the way that it reviews and provides premarket approval of Class III devices, as described above, perhaps because it too advertised its XTRAC laser as "FDA approved." Rather, PhotoMedex asserts Defendants falsely touted the Pharos as having 510(k) clearance. We do not address whether representing a Class II medical device as having "FDA approval" may be actionable on the grounds that these devices are not subject to the premarket approval process.

[4]The following are designated significant changes or modifications requiring premarket notification: "(i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process [or] (ii) A major change or modification in the intended use of the device." 21 C.F.R. § 807.81(a)(3).

> the device they should compare it to is their most recently cleared device . . . . In effect, manufacturers need to submit a new 510(k) only when a change, or the sum of the incremental changes exceeds the § 807.81(a)(3) threshold, "could significantly affect the safety or effectiveness of the device."

Id. (quoting from 21 C.F.R. § 807.81(a)(3)). Acknowledging that "[m]anufacturers may make modifications to a cleared device that do not require submission of a new 510(k)," the FDA instructs its reviewers "not [to] request information regarding changes observed in a new 510(k) that were previously implemented by industry without the requirement for 510(k) clearance, unless the lack of information regarding the previous modification(s) does not allow the [substantial equivalency] determination to be made." FDA, *The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry*, 2002 WL 32811431 (Oct. 4, 2002).

[8] It is significant that under the regulatory structure established by the FDA for the medical devices at issue in this case, clearance to market a given device did not necessarily require an affirmative statement of approval by the FDA. The FDA's previous clearance of the SurgiLight laser covered Defendants' Pharos device as well, as long as the Pharos was not significantly modified from the SurgiLight device. It was Ra Medical, as the manufacturer, that had the responsibility in the first instance for gauging whether the Pharos's departures from SurgiLight's cleared laser warranted a new 510(k) application. An affirmative confirmation by the FDA of the correctness of Defendants' decision not to submit an additional 510(k) application was not required.

Defendants argue that their license to produce a version of SurgiLight's FDA-cleared laser justified their statements that their Pharos laser had been cleared by the FDA. PhotoMedex argues, however, that there were "significant technological

differences" between SurgiLight's cleared laser and the Pharos, making a separate 510(k) submission necessary before it could be cleared for market.

The issue was presented to the FDA, but it does not appear that the agency ever reached the conclusion sought by PhotoMedex. Starting in August 2003, PhotoMedex, through its attorneys, wrote the FDA "to file a complaint" against Ra Medical for promoting the Pharos laser without FDA clearance, arguing the Pharos did not come within SurgiLight's license. PhotoMedex contacted the FDA numerous times over the following years, furnishing comparisons of the SurgiLight and Pharos lasers and urging the FDA to "take immediate enforcement action against Ra Medical." Each time the FDA responded by promising nothing more than that "we will evaluate this matter to determine what follow-up action is appropriate."

The FDA did write Irwin in September 2005, stating it noticed Ra Medical was marketing the "Pharos EX-308 Excimer Laser" for the treatment of psoriasis and vitiligo and asking him to provide the clearance number or explain why one was not needed since FDA records did not contain a clearance number for the Pharos. Irwin replied that the Pharos was cleared through its licensing agreement with SurgiLight, and he identified SurgiLight's associated FDA clearance numbers.

In October 2005, the FDA conducted an inspection of Ra Medical's manufacturing facility. The resulting "Establishment Inspection Report" specifically discussed the "comparability of the Pharos EX-308 Excimer Laser System with the SurgiLight EX-308 Excimer Laser System and whether [Ra Medical] needed to submit a new 510(k) for the Pharos EX-308." The investigating FDA agent noted:

> Mr. Irwin said he felt he was manufacturing essentially the same excimer laser, with insignificant dif-

> ferences. When asked about the differences in specifications, Mr. Irwin explained that they were irrelevant differences or in some cases the specifications in the SurgiLight 510(k) were not accurately reported. Because of the complexity in explaining the differences in specifications between the Pharos EX-308 and the SurgiLight EX-308, I asked Mr. Irwin if he would write an explanation of why he felt the specification differences did not warrant another 510(k) filing. Mr. Irwin said he would happily prepare such a document, and it [was] provided . . . . I said I could not make the determination as to whether or not the Pharos EX-308 Excimer Laser System needed a new 510(k) for going beyond the scope of the SurgiLight 510(k), but I would forward his comments to the reviewing division.
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> . . .
>
> Mr. Irwin said he planned to file a 510(k) expanding the indications for the Pharos Excimer Laser System in the near future.

The FDA subsequently sent Irwin a copy of the Establishment Inspection Report dated February 2006, explaining it had closed its inspection.

In September 2006, Ra Medical submitted a 510(k) notification to the FDA stating the Pharos "is intended for use in the treatment of psoriasis, vitiligo, atopic dermatitis, and leukoderma." Defendants argue that they filed this 510(k) submission only to gain clearance for the latter two uses since, in their view, the former two uses were already cleared based on the 501(k) clearance of SurgiLight's laser. In November 2006, the FDA responded by notifying Irwin that "you may not market your device until it has been cleared for marketing by the FDA." In January 2007, the FDA wrote Irwin saying it had "information that suggests" Ra Medical was manufacturing

and marketing the Pharos without marketing clearance in violation of the FDCA. Neither letter was explicit in stating whether it referred to marketing of the device for all four medical conditions or only the two new ones.

In early April 2007, the FDA responded to Ra Medical's 510(k) notification by stating that the Pharos could "proceed to the market" since it was substantially equivalent to legally marketed predicate devices. In this 510(k) clearance letter, the FDA also noted the Pharos "will be indicated for use for the treatment of psoriasis, vitiligo, atopic dermatitis and leukoderma." In the end, therefore, the FDA did not take any action against Defendants or limit the marketing of their Pharos device.

Nonetheless, PhotoMedex maintains that prior to the FDA's April 2007 letter Defendants did not have clearance to market the Pharos for treatment of psoriasis and vitiligo. PhotoMedex's Lanham Act claim depends upon its contention that the Pharos varied enough from SurgiLight's cleared laser to require a separate 510(k) filing. If a separate filing was not required, then the FDA's previous clearance of SurgiLight's device covered the Pharos, and Defendants' statements regarding FDA clearance of the Pharos were not false or misleading.[5]

[9] The statute assigns to the FDA the responsibility for taking enforcement action against Defendants. FDA action could have taken different forms, including a clear statement that the Pharos was not covered by the prior clearance of the SurgiLight laser, an effort to stop Defendants from marketing their Pharos device, or action to impose a civil monetary penalty. The FDA did none of those things, however.

[5]PhotoMedex's expert admits as much, opining that "the only device RA Medical could distribute as of March 13, 2003 was the SurgiLight EX-308 Excimer Laser, *or a laser that only exhibited an insignificant modification of that device*." (Emphasis added)

[10] 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. Accordingly, we affirm the district court's grant of summary judgment on this claim.

Our decision is consistent with other decisions refusing to allow private actions under the Lanham Act premised on enforcement determinations that the FDA and other regulatory agencies did not themselves make. For instance, the Third Circuit rejected a Lanham Act false advertising claim based on a cough syrup's label listing a demulcent ingredient as "inactive," a regulatory matter the FDA had not determined. *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230-32 (3d Cir. 1990). The court reasoned that "the Lanham Act does not create indirectly, at least not in cases requiring original interpretation of [the FDCA] or [its] accompanying regulations[,]" what the FDCA does not create directly. *Id.* at 231. *Sandoz* rightly observed that it would be inappropriate "for a court in a Lanham Act case to determine preemptively how a federal administrative agency will interpret and enforce its own regulations." *Id.*; *see also IQ Prods. Co. v. Pennzoil Prods. Co.*, 305 F.3d 368, 372-74 (5th Cir. 2002) (concluding the defendants' failure to label a product in keeping with Federal Hazardous Substances Act regulations was not actionable under the Lanham Act since the former does not authorize a private right of action); *Summit Tech., Inc. v. High-Line Med. Instruments Co.*, 933 F. Supp. 918, 934 (C.D. Cal. 1996) (affirming dismissal of a Lanham Act claim since "in order for this Court to test the truth of Defendant's apparent claim that it can legally import the Summit

lasers, the Court would be required to perform an 'original interpretation' of the FDA regulations governing this area" (quoting *Sandoz*, 902 F.2d at 231)). Testing the truth of PhotoMedex's claim would similarly require a court to usurp the FDA's prerogative to enforce the FDCA and to decide whether, under the FDCA and its regulations, the Pharos was similar enough to SurgiLight's laser to permit Defendants to rely on its 510(k) clearance.

Along similar lines, the D.C. Circuit concluded a cab company's statements that it was authorized to provide particular services under regulations promulgated by the D.C. Taxicab Commission could not form the basis of a Lanham Act claim. *Dial A Car, Inc. v. Transp., Inc.*, 82 F.3d 484, 488-90 (D.C. Cir. 1996). Rather, unless the regulations lack ambiguity, the court held alleged misrepresentations must have been preceded by "a clear and unambiguous statement *from the Taxicab Commission* regarding [defendants' legal] status before a Lanham Act claim can be entertained." *Id.* at 489 & n.3. The *Dial A Car* court finally noted that "[i]nstead of bringing this claim in federal court, [plaintiff] should be forced to take its argument to the D.C. Taxicab Commission and lobby the Commission to crack down on [defendants'] activities, assuming they are proscribed under [the regulations]." *Id.* at 490.

As in *Dial A Car*, the appropriate forum for PhotoMedex's complaints is the responsible regulatory agency. Permitting PhotoMedex to bypass the FDA and instead bring suit would require the court to make a decision the FDA chose not to make. *See Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993) (dismissing a Lanham Act claim asserting manufacturers impliedly falsely promoted their drugs as FDA approved by placing the drugs on the market); *see also Summit Tech., Inc. v. High-Line Med. Instruments Co.*, 922 F. Supp. 299, 305-07 (C.D. Cal. 1996) (deciding that failing "to disclose that [defendants'] re-imported used and/or modified Summit Excimer Laser Systems are not approved by the FDA" was not actionable under the Lanham Act when "the

FDA has not yet determined whether or not the re-imported Summit devices need further approval *at all*").

PhotoMedex cites *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934 (8th Cir. 2005), in support of its claim, but we do not view our conclusion to be at all inconsistent with that decision. The plaintiff in that case brought a Lanham Act claim against its competitor for falsely advertising that its antibiotic animal feed additives had been approved for certain uses by the FDA. Both the plaintiff and defendant had previously received interim FDA approval to market their respective additive products for certain uses, and that approval had been codified in a regulation. That regulation did not itself list the uses for which each company's product had been approved, however, but instead incorporated a statement of uses found in a different regulation. In the years that followed, the plaintiff obtained additional FDA approval to market its product for several new uses, which the FDA added to the list in the second regulation, naming the plaintiff as the only manufacturer who submitted information in support of approval. However, the first regulation was never amended to account for the FDA's later approval of new uses for the plaintiff's product. That gave the appearance of expanding the number of uses for which the defendant's product had been approved as well, though the defendant had never applied for or obtained such approval from the FDA for its product. The plaintiff brought an action against the FDA to remedy this situation. That action was resolved with a stipulated order of dismissal in which the FDA made it clear that there was no record of the defendant obtaining the FDA's approval for the additional uses. In addition, the FDA published notices of proposed rulemaking to eliminate the now obsolete first regulation and of the opportunity to be heard on the extent of the approvals given to defendant's product. *See id.* at 936-37. The Eighth Circuit reversed the district court's dismissal of the plaintiff's Lanham Act claim of false advertising, reasoning that in light of the FDA's prior guidance on the precise dispute, the claim would not require a preemptive interpretation

by the court of FDA regulations. *Id.* at 940; *accord Rhone-Poulenc Rorer Pharms. v. Marion Merrell Dow*, 93 F.3d 511, 516 (8th Cir. 1996) (affirming Lanham Act remedy where pharmaceutical company gave the false impression that its drug was FDA approved for a use the FDA admittedly had not approved).

Although the facts in *Alpharma* are complicated, the court's holding is clear. In that case, the FDA explicitly made clear that it had not given the defendant's product the affirmative approval required for expanding its list of permissible uses. Therefore, the court held, the plaintiff could bring a Lanham Act claim based on the defendant's false statements in its advertisement that the uses had been approved. In contrast to *Alpharma*, the FDA never concluded or clearly stated that the Pharos lacked premarket clearance for psoriasis and vitiligo. As described above, the regulatory 510(k) clearance scheme for Class II devices put the responsibility on Ra Medical to decide in the first instance whether and when a new 510(k) application had to be filed. That the FDA may have asked questions about the Pharos's clearance status does not demonstrate that the FDA ever concluded that Ra Medical was wrong in its determination that the clearance given to SurgiLight's laser device covered the Pharos laser as well. Instead, the FDA closed its inspection in February 2006 without speaking to the Pharos's clearance status or taking disciplinary action.

After Defendants submitted a 510(k) submission in September 2006, the FDA wrote in January 2007 that it had "information that suggest[ed]" the Pharos was being marketed without clearance. *Cf. Alpharma, Inc.*, 411 F.3d at 936 (noting in response to plaintiff's lawsuit against it, the FDA filed a stipulation stating it lacked any record of approving the defendant's product for the uses in question). About two months later, the FDA completed its review of Defendants' 510(k) notification and made a substantial equivalence determination, thereby clearing the Pharos laser for marketing without

stating or even suggesting that there had been any prior period of noncompliance.

Validating PhotoMedex's position "would require us to usurp [the FDA's] responsibility for interpreting and enforcing potentially ambiguous regulations." *Sandoz*, 902 F.2d 231. That PhotoMedex engaged in an extensive campaign to try to convince the FDA to act on Ra Medical's supposed misstatements and violations demonstrates that PhotoMedex understood that this subject fell within the FDA's domain.

The actions the FDA took in this case do not indicate that the agency ever concluded that the clearance for SurgiLight's device did not cover the Pharos device.[6] The FDA ultimately cleared the Pharos, elected not to find any violation, and did not seek to impose any other penalty on Defendants. The FDCA explicitly says that enforcement power is reserved to the federal government. To permit PhotoMedex to proceed with a claim that Defendants violated this law when the FDA did not so determine would, in effect, permit PhotoMedex to assume enforcement power which the statute does not allow and require the finder of fact to make a decision that the FDA itself did not make.

We therefore affirm the order of summary judgment for the claims based on Defendants' statements that the Pharos had FDA clearance.[7]

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[6]Because the FDA never took action regarding Ra Medical's device, we need not address the question of whether later action by the FDA might have permitted PhotoMedex to pursue a claim under the Lanham Act based on statements made by Ra Medical prior to the FDA's action.

[7]PhotoMedex does not argue that it would be able to pursue state law claims for false advertising of FDA clearance even if its Lanham Act claim fails.

B. Claims Regarding the Pharos Release Date

PhotoMedex asserts that Defendants knowingly misrepresented in March 2003 that the Pharos laser would be available that summer, within just a few months. Defendants admit they did not ship the first Pharos until September 2004, more than a year later, but argue that they were delayed in part by having to defend against PhotoMedex's multiple lawsuits.

The district court interpreted the predictions of the Pharos's release date to be mere statements of opinion regarding future events, which are generally not actionable. *See Bayview Hunters Point Cmty. Advocates v. Metro. Trans. Comm'n.*, 366 F.3d 692, 698 (9th Cir. 2004) ("[P]redictions as to future events are ordinarily non-actionable expressions of opinion under basic principles of the tort of fraudulent misrepresentation." (internal quotation marks omitted)); *see also Coastal Abstract Serv., Inc. v. First Am. Title Ins. Co.*, 173 F.3d 725, 731 (9th Cir. 1999) ("Statements of opinion are not generally actionable under the Lanham Act."); *Richard P. v. Vista Del Mar Child Care Serv.*, 165 Cal. Rptr. 370, 373 (Cal. Ct. App. 1980) (noting that ordinarily "predictions as to future events are deemed expressions of opinion, and thus not actionable").

[11] There is, however, a well-established exception — if "the speaker has knowledge of facts not warranting the opinion." *Id.*, 165 Cal. Rptr. at 373. An honest or sincere statement of belief about a future event is not actionable, but a statement known at that time by the speaker to be false, or a statement by a speaker who lacks a good faith belief in the truth of the statement, may constitute an actionable misrepresentation. *See id.*; *see also Harris v. United States*, 48 F.2d 771, 781 (9th Cir. 1931) (holding defendant's misrepresentation that a stock purchase was a good investment was actionable fraud rather than a mere expression of opinion or statement of a future event "where the buyers have no independent knowledge of any of the facts with relation to the [investment]") In this instance, Defendants may be liable for

misrepresentation if they said that the Pharos would be available in August 2003 but knew that it would not or could not actually be available until a substantially later date.

Typically, "[w]hether a statement is nonactionable opinion or actionable misrepresentation of fact is a question of fact for the jury." *Furla v. Jon Douglas Co.*, 76 Cal. Rptr. 2d 911, 918 (Cal. Ct. App. 1998). The district court determined PhotoMedex "offer[ed] no evidence of malfeasance surrounding Defendants' [release] estimation" on which a jury could find for it. Our review of the evidence, which on summary judgment must be viewed in favor of the non-moving party, in this case PhotoMedex, indicates otherwise.

Irwin informed FDA officials that "Phase II was started in March 2003, at which time [Ra Medical] developed a design plan." PhotoMedex's expert opined that:

> In my experience, to move a medical laser from the beginning of design Phase II to production would typically require 12 to 18 months, assuming that the Phase I work was complete and well-documented. My review of the documentation generated before March 2003 shows no evidence . . . that the Phase I work was complete and well-documented. Ra Medical's documentation primarily shows only rudimentary documentation of internal laser research and development. It is therefore my opinion that Ra Medical would have found it impossible to bring the Pharos laser through the remaining design Phases II, III and IV, the preproduction phase and enter production by either the 'summer' or August of 2003. It is also my opinion that it was unreasonable and misleading for the Defendants to project the estimated delivery date of the Pharos laser for any time in 2003, but would have been reasonable for the Defendants to project their estimated delivery date of the Pharos laser to be sometime in the latter half of

> 2004. Ra Medical did, in fact, ship its first laser in September 2004. . . . It is also my opinion that a person with experience in medical device development and manufacturing, specifically the development and manufacture of excimer lasers, would and should know the reasonable timetable for completion and shipment of a new excimer laser product.

We conclude that this evidence suffices to raise a genuine issue of material fact as to whether Defendants intentionally misrepresented the Pharos's release date.

[12] The potential motivation for and harm from such a misrepresentation is obvious. By telling prospective purchasers that the Pharos would be available soon, Defendants might have persuaded them not to buy PhotoMedex's device, which was already available, leaving them open to consider and possibly purchase Defendants' competing product later. *Accord Newcal Indus.*, 513 F.3d at 1053-54 (reversing dismissal of Lanham Act claims involving a copier machine lessor's statement that its contract terms were limited to 60 months, holding whether the lessor knew at the time that it would extend the contractual terms was a factual question). Accordingly, we vacate summary judgment for the claims based on Defendants' statements that the Pharos would be available in the summer of 2003 and remand those claims for further proceedings.

C. Claims Regarding Irwin's Role as the Inventor of PhotoMedex's Laser Device

PhotoMedex asserts that Defendants deceptively proclaimed Irwin was "inventor" of the XTRAC, i.e., that Irwin was the only, or at least the primary, inventor of the entire XTRAC laser system. Defendants respond that Irwin served as vice president of engineering at PhotoMedex where he "was intimately involved in the development of the XTRAC

system." Defendants also identify Irwin as the inventor of particular components of the XTRAC in patents.

[13] Defendants' commercial depiction of Irwin as "inventor" of the XTRAC is actionable to the extent it misled consumers into believing that Irwin was the sole inventor or made more than his actual share of inventive contributions. *See Cook, Perkiss & Liehe, Inc. v. N. Cal. Collection Serv., Inc.*, 911 F.2d 242, 245 (9th Cir. 1990) ("[A] false advertising cause of action under the [Lanham] Act is not limited to literal falsehoods; it extends to false representations made by implication or innuendo."); *see also Ariz. Cartridge Remanufacturers Ass'n, Inc. v. Lexmark Int'l, Inc.*, 421 F.3d 981, 985-86 (9th Cir. 2005) (same for California state law actions). Calling Irwin the "inventor of the XTRAC" might have been misleading. Evidence supplied by PhotoMedex shows that Irwin was only named as an inventor in patents for XTRAC's cooling apparatus and that other individuals designed the bulk of the XTRAC system. Thus, we vacate summary judgment for the claims relating to Defendants' representations that Irwin was the inventor of the XTRAC and remand those claims for further proceedings.

III. Conclusion

In sum, we affirm summary judgment on PhotoMedex's claim that Defendants misrepresented the FDA's clearance of their product. We conclude, however, that summary judgment should not have been granted on PhotoMedex's claims based on Defendants' alleged misrepresentations about when its Pharos product would be put on the market and Irwin's role as inventor of PhotoMedex's laser device. Those claims are remanded for further proceedings.

Each party shall bear its own costs on appeal.

AFFIRMED in part; VACATED in part; and REMANDED for further proceedings.