

**SEP 10 1999**

**PATRICK FISHER**  
Clerk

**PUBLISH**

**UNITED STATES COURT OF APPEALS**  
**TENTH CIRCUIT**

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COTTRELL, LTD., a Colorado  
corporation,

Plaintiff-Appellant,

v.

BIOTROL INTERNATIONAL, INC.,  
a Delaware corporation, and  
PRO-DEX, INC., a Colorado  
corporation,

Defendants-Appellees.

No. 97-1475

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**Appeal from the United States District Court  
for the District of Colorado  
(D.C. No. 97-S-1479)**

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Aurora, Colorado.

Richard A. Johnson (Julie S. Schoenfeld with him on the brief), Porzak Browning  
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Before **EBEL**, **BRISCOE** and **LUCERO**, Circuit Judges.

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**EBEL**, Circuit Judge.

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Cottrell, Ltd. (“Cottrell”) filed a Lanham Act claim against Pro-Dex, Inc. (“Pro-Dex”), and its wholly-owned subsidiary, Biotrol International, Inc. (“Biotrol”), alleging that they made false and misleading representations with regard to their hard surface cleaning product, “Birex.” The district court granted the defendants-appellees’ motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6). We now reverse and remand.

## **BACKGROUND**

The parties to this litigation manufacture, advertise, and market hard surface cleaners and disinfectants for use in medical and dental facilities. Because the parties’ products are antimicrobial pesticides, the cleaners and disinfectants are regulated by the Environmental Protection Agency (“EPA”), which must review and approve the text of all labels (“label claims”) on or accompanying the products before they can be sold. See 7 U.S.C. §§ 136 & 136a. As such, manufacturers and sellers of hard surface cleaners and disinfectants are forbidden by law from using label claims which have not been approved by and registered with the EPA. See 7 U.S.C. §§ 136a(c)(1) & 136j(a)(1)(B) (“it shall be unlawful for any person . . . to distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person . . . any registered pesticide if any claims made for it as a

part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration under section 136a of this title,” which requires pesticide registrants to file with the EPA administrator “a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use,” in order to qualify for approval).<sup>1</sup>

Cottrell sued Pro-Dex and Biotrol (collectively “defendants-appellees”), claiming that representations made by defendants-appellees regarding their hard surface cleaner and disinfectant, which is sold under the name “Birex,” violated section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a). Specifically, Cottrell alleged in its complaint that the defendants-appellees’ label claims were “violative of EPA clearance” and “[a]s such . . . false,” and that the label claims deceptively imply that “EPA approval or clearance has been obtained.” The

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<sup>1</sup>Title 7 U.S.C. §§ 136-136y (“Federal Insecticide, Fungicide, and Rodenticide Act” or “FIFRA”) and 40 C.F.R. §§ 152 provide a detailed regulatory framework for registering pesticides (including antimicrobial pesticides like the parties’ hard surface cleaners and disinfectants), including provisions for approving pesticide labels and claims made therein. FIFRA prohibits, *inter alia*, the distribution, sale, receipt or delivery of pesticides which have not complied with the registration requirements, *see* 7 U.S.C. § 136a(a), and makes unlawful selling “any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration under section 136a of this title,” 7 U.S.C. § 136j(a)(1)(B).

defendants-appellees filed a motion to dismiss pursuant to Fed. R. Civ. P.

12(b)(6), which the magistrate judge recommended granting, stating:

Plaintiff's allegations that the claims are false are based on the allegation that the claims violate the EPA clearance of the product. The complaint does not specifically allege, however, that Defendants' claim that the efficacy of Birex continues for seven days after mixing is actually false or misleading. Thus, resolution of Plaintiff's claims would involve the determination of whether the claim that the efficacy of the product continues for seven days after mixing violates the EPA clearance. Similar to the Mylan [Labs., Inc. v. Matkari, 7 F.3d 1130 (4th Cir. 1993)] case, for purposes of a Lanham Act misrepresentation claim, it cannot be implied from the fact that the product has been placed on the market that the EPA has approved Defendants' label claims. An affirmative representation is required. Mylan, 7 F.3d at 1139. Based on the above case law, absent an allegation that the Defendants' claim regarding the efficacy of Birex is false, Plaintiff has failed to state a claim under section 43(a) of the Lanham Act.

Cottrell objected to the magistrate judge's recommendation, but "agreed that an expansion of the existing factual predicate for its claims is warranted." Accordingly, Cottrell filed a motion for leave to file an amended complaint. Cottrell's proposed amended complaint alleged that the defendants-appellees affirmatively misrepresented that the EPA gave "clearance and/or approval" to claims made in Birex literature that "proper use is to discard weekly," and that "Biotrol's product is not known to be effective for that period of time [one week], nor has it been demonstrated to be effective under those use conditions [weekly discarding]."

The district court accepted the magistrate judge’s recommendation to grant the defendants’ motion to dismiss and denied Cottrell’s motion for leave to file an amended complaint despite recognizing that “Fed. R. Civ. P. 15(a) requires leave to amend be given freely,” on the ground “that the Proposed Amended Complaint suffers from the same defect as the original complaint.” The district court identified the “defect” it found in Cottrell’s original and proposed amended complaint as follows: “[T]his complaint seeks a determination whether the label claims [of the defendants] violate the EPA clearance. Resolution of the Plaintiff’s complaint would require the court to interpret and apply regulations that are exclusively within the province of the EPA.”

Cottrell now appeals the district court’s grant of the motion to dismiss and denial of its motion for leave to file an amended complaint. We reverse and remand.

## DISCUSSION

### **Whether the District Court Erred in Dismissing Cottrell’s Lanham Act Claim.**

#### *A. Standard of Review*

“We review de novo a district court’s dismissal of a cause of action for failure to state a claim upon which relief can be granted.” Chemical Weapons Working Group, Inc. v. United States Dep’t of the Army, 111 F.3d 1485, 1490

(10th Cir. 1997). “We uphold a dismissal under Fed. R. Civ. P. 12(b)(6) only when it appears that the plaintiff can prove no set of facts in support of the claims that would entitle him to relief, accepting the well-pleaded allegations of the complaint as true and construing them in the light most favorable to the plaintiff.” Yoder v. Honeywell Inc., 104 F.3d 1215, 1224 (10th Cir.) (quotations omitted), cert. denied, 118 S. Ct. 55 (1997). “[T]he Federal Rules of Civil Procedure erect a powerful presumption against rejecting pleadings for failure to state a claim.” Cayman Exploration Corp. v. United Gas Pipe Line Co., 873 F.2d 1357, 1359 (10th Cir. 1989) (quotations omitted). Granting defendant’s motion to dismiss is “a harsh remedy which must be cautiously studied, not only to effectuate the spirit of the liberal rules of pleading but also to protect the interests of justice.” Id. (quotations omitted).

*B. Merits*

Cottrell argues that both its original and proposed amended complaint properly alleged all the elements necessary to make out a claim under the Lanham Act.<sup>2</sup> Section 43(a) of the Lanham Act as amended reads, 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 word,

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<sup>2</sup>Because we reverse the district court’s dismissal of Cottrell’s original complaint, we do not reach issues concerning the proposed amended complaint.

term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which —

(A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or

(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). Thus, as the district court recognized, in order to state a claim under § 43(a) of the Lanham Act,<sup>3</sup> a plaintiff must allege: (1) that defendant made material false or misleading representations of fact in connection with the commercial advertising or promotion of its product, see Abbott Labs. v. Mead Johnson & Co., 971 F.2d 6, 13 (7th Cir. 1992) (“Section 43(a)(2) of the

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<sup>3</sup>The Act “principally provides for two distinct causes of action: false designation of origin or source, known as ‘product infringement,’ and false description or representation, known as ‘false advertising.’” Resource Developers, Inc. v. Statute of Liberty-Ellis Island Found., Inc., 926 F.2d 134, 139 (2d Cir. 1991) (quoting Johnson & Johnson v. Carter-Wallace, Inc., 631 F.2d 186, 188 (2d Cir. 1980)); see also Stanfield v. Osborn Indus., Inc., 52 F.3d 867, 873 (10th Cir. 1995) (“There are two distinct bases of liability under section 1125: (1) false representation in advertising concerning the qualities of goods (false advertising claims); and (2) false representations concerning the origin or endorsement of goods (false association or product infringement claims).”).

[Lanham] Act prohibits the use of false or misleading statements or representations of fact in commercial advertising, and establishes a private remedy for any violation thereof.”); Sandoz Pharms. v. Richardson-Vicks, Inc., 902 F.2d 222, 231 (3d Cir. 1990); (2) in commerce; (3) that are either likely to cause confusion or mistake as to (a) the origin, association or approval of the product with or by another, or (b) the characteristics of the goods or services; and (4) injure the plaintiff. See generally Charles E. McKenney & George F. Long III, *Federal Unfair Competition: Lanham Act § 43(a)*, § 6 (11th release 1998).

The dispute in this case involves only whether the plaintiff properly alleged the first requirement.<sup>4</sup> As the Second Circuit has explained, “Section 43(a) of the Lanham Act encompasses more than literal falsehoods,” because otherwise, “clever use of innuendo, indirect intimations, and ambiguous suggestions could shield the advertisement from scrutiny precisely when protection against such sophisticated deception is most needed.” American Home Prods. Corp. v.

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<sup>4</sup>Cottrell’s complaint sufficiently alleged the other three elements. In paragraph 20 of the complaint, Cottrell alleged misrepresentations in commerce. (“The misrepresentations made by the Defendants Biotrol and Pro-Dex have been made in commerce.”) In paragraph 16, Cottrell alleged that “customers have been actually deceived by advertising and promotional materials published by and continuing to be published by Biotrol and Pro-Dex [by falsely implying EPA approval of the label].” Finally, in paragraphs 19 and 21, Cottrell alleged sufficient injury. (“Defendants Biotrol and Pro-Dex’s material misrepresentations injure Cottrell by causing Cottrell to lose customers and sales, resulting in business losses . . . .”); (“The actions of Defendants Biotrol and Pro-Dex have and are likely to continue to cause Cottrell irreparable harm.”)

Johnson & Johnson, 577 F.2d 160, 165 (2d Cir. 1978). To assess the truth or falsity of these latter, more amorphous, misleading statements, “the courts favor testing by consumer reaction surveys, but have also found falsity based on their own independent reaction and the reaction of witnesses testifying before the court, including testimony based on test results, consumer surveys, complaints received, allegations of more than a few instances of misrepresentation, and otherwise.” McKenney & Long, supra, § 6.03[2], at 6-27 to 6-28 (citing cases) (footnotes omitted). Notwithstanding the various methods for testing the accuracy of allegedly misleading advertising, we reiterate that when considering a motion for dismissal under 12(b)(6), we must assume all facts as alleged.

In its original complaint, Cottrell alleged that the defendants-appellees made material false or misleading representations, as follows:

12. Standardized “label claims” as to efficacy for products such as Birex include how long a solution may be used after mixing and dilution. Birex’s approved and cleared “label claims” require that it be “mixed and used daily” according to the approved labels on file with the EPA.<sup>5</sup>

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<sup>5</sup>We note that on appeal the defendants-appellees assert that: “In fact, Birex is not approved for a mix and use daily label claim, it is approved for a claim that states ‘[a]s solution becomes dirty, discard and replace with a fresh one . . . .’” And, in a motion for attorney’s fees filed by defendants-appellees in the district court, defendants-appellees attached as an exhibit Birex’s approved label which appears to support defendants-appellees’ position. However, because this case comes to us on appeal from 12(b)(6) dismissal for failure to state a claim on which relief can be granted, we must accept all the well-pleaded allegations of the  
(continued...)

13. Contrary to the provisions and requirements of its “label claims” as approved by the EPA, Biotrol, through its product information material and its sales force, has and continues to assert in the context, *inter alia*, of commercial advertising or promotion that the efficacy of Birex continues for seven days after mixing.

15. Biotrol, under the direction and control of Pro-Dex, has continued to advertise, market and sell its Birex product under that and various other names with the full knowledge that the claims made are violative of EPA clearance. As such, these Defendants’ advertising and promotional materials and claims as included with the products themselves, as well as on product information sheets and through sales persons, are false.

16. The Defendants Biotrol and Pro-Dex’s material representations in commercial advertising and promotion has been disseminated to their customers and potential customers, many if not all of whom are also customers or potential customers of Cottrell. Such customers have been actually deceived by the advertising and promotional materials published by and continuing to be published by Biotrol and Pro-Dex. Said claims and misrepresentations further deceive existing and potential customers of the parties by implying that EPA approval or clearance has been obtained therefor.

17. Customers for hard surface disinfectants are attracted by “label claims” which provide for “mixing and using” over longer periods of time. By making false label claims, *inter alia*, that Birex can [be] used for seven days after mixing, Biotrol and Pro-Dex place Cottrell at a gross, substantial and continuing competitive disadvantage. Because false and incorrect label claims make their products appear to be more attractive to customers and ultimately end users of these products, the Defendants misrepresentations are likely to influence the purchasing decisions of the persons and entities to whom disseminated.

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<sup>5</sup>(...continued)  
complaint as true.

The defendants-appellees argue that “FIFRA is the exclusive federal law that regulates the labeling of pesticides,” that “Birex is regulated as a pesticide under [FIFRA],” and that Cottrell’s allegations relate only to Birex’s label claims. Thus, they argue that Cottrell is attempting to do indirectly what Congress has not given it the right to do directly — i.e., enforce the requirements of FIFRA (which only the EPA can do) by way of the Lanham Act. Moreover, the defendants-appellees argue that resolution of Cottrell’s claims would require a determination of whether the label claims violate EPA clearance — a determination requiring EPA expertise, which only the EPA is qualified to make. Accordingly, the defendants-appellees claim that Cottrell has failed to state a claim on which relief can be granted in the courts.

Cottrell argues that it is not attempting to enforce FIFRA, but rather to vindicate its rights under the Lanham Act independent of FIFRA. We agree.

Construing Cottrell’s complaint in the light most favorable to Cottrell, we recognize at least three allegations of false or misleading statements made by defendants-appellees which, for purposes of this opinion, we characterize as claims #1, #2 and #3: #1, that representations made in Birex’s advertisements violate the EPA clearance obtained under FIFRA by claiming that Birex continues to be an effective cleaner and disinfectant for seven days; #2, that Birex’s advertising deceives customers “by implying that EPA approval or clearance has

been obtained [for the seven-day efficacy claim]”;<sup>6</sup> and #3, that Birex’s claim that it “can be used seven days after mixing” is factually false.

In resolving defendants-appellees motion to dismiss, the district court focused on paragraph 15 of Cottrell’s complaint, which contained only allegations of the first category of falsity that we have identified (claim #1 in the preceding paragraph). Based on allegations contained therein, the district court “agree[d] with the Recommendation [of the magistrate judge] that this complaint seeks a determination whether the label claims violate the EPA clearance. Resolution of the Plaintiff’s complaint would require the court to interpret and apply regulations that are exclusively within the province of the EPA.” According to the district court, this was contrary to the teaching of Mylan Labs., Inc. v. Matkari, 7 F.3d 1130, 1139 (4th Cir. 1993); Sandoz Pharms., 902 F.2d at 231; Summit Tech., Inc. v. High-Line Med. Instruments, Co., 933 F. Supp. 918, 933 n.7 (C.D. Cal. 1996); Grove Fresh Distribs., Inc. v. Flavor Fresh Foods, Inc., 720 F. Supp. 714, 715-16 (N.D. Ill. 1989). We agree with the district court that claim #1 is subject to 12(b)(6) dismissal. However, in our view the district court failed to recognize the

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<sup>6</sup>Claims #1 and #2 are closely related but distinct. As we discuss further below, claim (1) is an allegation that Birex’s label claims violate FIFRA, related regulations, and EPA actions taken pursuant to FIFRA. As such, claim #1 is an impermissible attempt under the Lanham Act to enforce FIFRA’s substantive provisions. Claim #2, on the other hand, focuses on Birex’s representations directed at consumers, and asserts that Birex’s label claims put in commerce a false representation of EPA approval (which Cottrell argues had not been given).

second and third categories of alleged falsity we have identified (claims #2 and #3 in the preceding paragraph). We reverse the district court's dismissal of Cottrell's case because we find that Cottrell alleged sufficient facts regarding claims #2 and #3 to state a claim under the Lanham Act.

We find instructive an unpublished memorandum and order from the United States District Court for the District of Kansas which addressed similar issues in a case involving the interaction between the Lanham Act and the federal Food, Drug, and Cosmetic Act ("FDCA"). See Braintree Labs., Inc. v. Nephro-Tech, Inc., No. 96-2459-JWL, 1997 WL 94237 (D. Kan. Feb. 26, 1997). There, the plaintiff contended that "the 'dietary supplement' designation on defendants' product [which had not obtained approval for marketing as a drug by the federal Food and Drug Administration ("FDA")] constitute[d] a false or misleading description in violation of section 43(a) of the Lanham Act. Defendants argue[d] that this claim may not stand because it merely alleges a violation of FDCA, for which no private right of action exists." Id. at \*2 (citation and footnote omitted). After discussing Sandoz Pharms., Mylan Labs., Grove Fresh Distributions, and Summit Tech, the court observed that "[a] general framework may be gleaned from these cases." Id. at \*6. The court noted that:

Affirmative misrepresentations . . . are generally actionable under the Lanham Act, even if the product is regulated by the FDA. Most obviously, a false statement of FDA approval is actionable. It is also clear that, because no private right of action exists under the FDCA,

a plaintiff may not use the Lanham Act as an alternative vehicle by which to seek redress for an FDCA violation. Moreover, claims that require direct interpretation and application of the FDCA are not properly recognized because such matters are more appropriately addressed by the FDA, especially in light of Congress's intention to repose in that body the task of enforcing the FDCA. The court believes that the Tenth Circuit would embrace these general principles.

Id. Ultimately, in Braintree Labs., the court concluded that the issue of whether the defendants' product's claim to be a "dietary supplement" was false or misleading involved interpretation and application of the FDA definition of "dietary supplement"; thus the court granted defendants' motion to dismiss plaintiff's Lanham Act claim. See id. at \*7.

The framework announced in Braintree Labs. serves us well in this case. As to Cottrell's claim that we have denominated #1, we agree with the district court that it must be dismissed. First, no party challenges the district court's conclusion that "FIFRA is exclusively enforced by the [EPA]," and thus we accept this proposition for the purposes of this appeal. See Almond Hill Sch. v. United States Dep't of Agriculture, 768 F.2d 1030, 1035-38 (9th Cir. 1985) (stating that "FIFRA does not authorize explicitly or implicitly a private cause of action to enforce the Act."); Fiedler v. Clark, 714 F.2d 77, 79 (9th Cir. 1983) (noting that FIFRA contains no explicit provision for private enforcement and "legislative history confirms that Congress did not intend to create a private cause of action under FIFRA," specifically citing Congress' rejection of a proposed

provision permitting private enforcement suits). Thus, this case is like Braintree Labs. because the EPA stands in a similar enforcement relationship to FIFRA as the FDA does to the FDCA. Second, we believe that Cottrell's claim #1 is properly characterized as an attempt to enforce FIFRA's labeling requirements. The "EPA clearance" that Cottrell claims Birex's advertisement violates was obtained pursuant to (and only because of) FIFRA. See Lowe v. Sporicidin Int'l., 47 F.3d 124, 130 (4th Cir. 1995) ("[I]t is clear that there is a 'FIFRA-created duty' to file 'a statement of all [label] claims' made for a pesticide with the EPA, § 136(c)(1)(C), and *not* to make 'any claims for it as a part of its distribution or sale' that 'substantially differ from any claims made for it as a part of th[at] statement.' § 136j(a)(1)(B).") (first two alterations ours, others in original)). Independent of FIFRA, an allegation that Birex's claims of seven-day efficacy violates EPA clearance has no force because independent of FIFRA no EPA clearance or approval for label claims would be necessary. Moreover, we believe that a determination of the scope of EPA clearance, and whether Birex's advertisement violates that clearance, would require EPA expertise. Finally, and most simply, even reading all inferences in Cottrell's favor, claim #1 fails to allege any false advertising. Accordingly, we agree with the district court that Cottrell must not be permitted to bring a FIFRA claim dressed up as a Lanham

Act claim, and claim #1 must be dismissed. Cf. Mylan Labs., 7 F.3d at 1139; Sandoz Pharms., 902 F.2d at 231.

As to claims #2 and #3, however, we believe Cottrell has alleged sufficient facts to support a Lanham Act claim independent of FIFRA. As identified above, claim #2 alleges that Birex's advertising deceives customers "by implying that EPA approval or clearance has been obtained [for the seven-day efficacy claim]."<sup>7</sup> As noted above, this claim is distinct from claim #1 because in addition to alleging that the label claims did not comport with FIFRA regulations and EPA approval, claim #2 adds an allegation that Birex's label claim, in the context in which the product is advertised, deceives consumers into believing, erroneously, that the EPA has approved Birex's one-week efficacy claim. As Braintree Labs. stated: "Most obviously, a false statement of [EPA] approval is actionable." Braintree Labs, 1997 WL 94237, at \*6; see also Mylan Labs., 7 F.3d at 1138-39 (in general an allegation of false label claim of FDA approval is sufficient to survive dismissal under Rule 12(b)(6), but there it was insufficiently alleged "that defendants[ explicitly] falsely represented that their drugs had been 'properly approved by the FDA'" and "that fatal deficiency cannot be cured by contentions

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<sup>7</sup>We note that an allegation of a mere implication of EPA approval approaches the type of abstract and unspecific allegation that courts correctly consider to be insufficient to survive 12(b)(6) dismissal. Thus, unless Cottrell demonstrates how defendants-appellees "imply" EPA approval, this claim still might be ripe for dismissal prior to trial.

that the very *act* of placing a drug on the market, with standard package inserts often used for FDA-approved drugs, somehow implies (falsely) that the drug had been ‘properly approved by the FDA.’”). If Cottrell can establish by consumer surveys or other means that Birex’s advertising is likely to confuse or actually confuses consumers, then the effect of the false “implication” of EPA approval that Cottrell now asserts could be as damaging for Lanham Act purposes as an express false claim of EPA approval. Thus, in the posture this case now stands, Cottrell has sufficiently alleged a material misrepresentation under the Lanham Act.

Defendants-appellees, however, would have us dismiss this case because Cottrell’s Lanham Act claim touches on issues covered by FIFRA. That is, because FIFRA prohibits the sale and distribution of products with unapproved or materially altered labels, defendants-appellees claim that FIFRA should preclude an independent Lanham Act claim. But, because FIFRA nowhere explicitly precludes Lanham Act coverage, we refuse to limit the scope of the Lanham Act absent circumstances that inherently require interpretation of FIFRA regulations and/or EPA approvals. Cf. Marriott Corp. v. Great America Serv. Trades Council, 552 F.2d 176, 180-81 (7th Cir. 1977) (refusing to dismiss Lanham Act claim involving “labor dispute,” and rejecting argument that Labor Management Relations Act gives exclusive jurisdiction to the National Labor Relations Board

because “[t]he fact that conduct is involved which may tangentially be covered by section 7 or 8 of the Labor Management Relations Act is not sufficient to preempt jurisdiction over Marriott’s [Lanham Act] trademark action”); see also McKenney & Long, supra, § 2.02, at 2-7 to 2-10 & nn. 10-19.2 (citing conflicting cases). While there might be cases which would require EPA expertise to determine whether claims made for a product were approved by the EPA, that fact is not evident from the complaint before us in this case, and at this early stage of pleadings we will not construe Cottrell’s claim #2 to involve such an allegation. Claim #2 can be construed to contend simply that the defendants-appellees falsely imply that the EPA has approved their claim that Birex is effective for seven days after mixing when in fact the EPA has not given such approval. We believe courts are capable of resolving such issues. Cf. Grove Fresh Distribs., 720 F. Supp. at 715-16 (despite fact that FDA regulation provides definition of “orange juice from concentrate,” court was capable of resolving plaintiff’s Lanham Act claim that defendants falsely claimed their product was “100% orange juice from Concentrate” without reference to agency definition or expertise). Accordingly, as to claim #2, Cottrell has stated a claim under the Lanham Act on which relief can be granted and the Rule 12(b)(6) dismissal must be reversed.

Likewise, Cottrell’s claim #3 — that defendants-appellees falsely represent that Birex “can be used seven days after mixing” — alleges sufficient facts to

state a claim under the Lanham Act and is not the proper subject for Rule 12(b)(6) dismissal. Admittedly, Cottrell’s assertion that “[b]y making false label claims, *inter alia*, that Birex can [be] used for seven days after mixing,” is not the most clear and direct way Cottrell could have alleged falsity. However, construing this claim in the light most favorable to Cottrell, we must conclude that it sufficiently alleges that the defendants-appellees falsely represent the efficacy of Birex. This type of claim — alleging that Birex’s label claims misrepresent facts concerning the quality of the product — is at the core of what the Lanham Act “false advertising” prohibition makes actionable. And again, although there may be circumstances under which EPA expertise would be necessary to determine the efficacy and longevity of Birex, from the naked pleadings alone we cannot say for certain that this is such a case. Accordingly, we reverse the Rule 12(b)(6) dismissal as to claim #3.

### **CONCLUSION**

We REVERSE the district court’s dismissal of Cottrell’s complaint pursuant to Rule 12(b)(6), and REMAND this case for further proceedings.<sup>8</sup>

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<sup>8</sup>Because we reverse the district court’s dismissal of Cottrell’s original complaint, we offer no opinion as to whether the district court erred in denying Cottrell’s motion for leave to file an amended complaint.