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Preclusion, Primary Jurisdiction, and Private Enforcement: The Intersection of the Lanham Act and the Federal Food, Drug, and Cosmetic Act



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Manufacturers of products regulated by the Food and Drug Administration (FDA), such as foods, drugs, devices, cosmetics and dietary supplements, often disagree with the promotional and marketing practices of their competitors. For example, a manufacturer may believe that a competitor is falsely advertising that it has obtained ''approval'' from FDA to market its product, or that the competitor's advertising is overstating the safety or efficacy of a product.

The manufacturer may also believe that these marketing practices violate the Federal Food, Drug, and Cosmetic Act (FFDCA).[1] As a result, the manufacturer may complain to FDA about the competitor's allegedly unlawful conduct. As is often the case, however, prompt enforcement action by FDA against the competitor may not be forthcoming.[2]

Another potential avenue for manufacturers to challenge objectionable advertising is the Lanham Act, a federal statute that prohibits false or misleading statements in commercial advertising and promotion.[3] Because the FFDCA may only be enforced by the government,[4] however, a threshold issue that commonly arises in Lanham Act cases involving an FDA-regulated product is whether the action should be permitted at all. Courts in Lanham Act cases involving FDA-regulated products have frequently determined that a particular claim is ''precluded'' by the FFDCA or otherwise falls within FDA's ''primary jurisdiction.'' Just as often, however, courts have rejected such defenses and allowed the case to proceed on the merits. These various decisions can seem inconsistent and even contradictory.

This term, the Supreme Court, for the first time, will address the intersection between the Lanham Act and the FFDCA.[5] The case on review involves a challenge to the labeling of a juice product regulated as a food under the FFDCA.

This article attempts to make sense of the complex landscape of cases addressing the intersection of the

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[1] 21 U.S.C. §§ 301 *et seq.*

[2] FDA follows a policy of confidentiality regarding enforcement matters. *Cf.* 5 U.S.C. § 552(b) (exempting certain agency materials from disclosure under the Freedom of Information Act). As a result, unless and until FDA publicly initiates enforcement, such as issuing, and publishing, a warning letter to the company in question, it is typically difficult, if not impossible, for a complainant to know whether FDA (i) has determined not to take any action in response to the complaint, (ii) has determined to initiate an investigation into the subject matter of the complaint, but has not yet reached any decision about whether to take enforcement action or (iii) has not yet determined whether to take any action, including initiating an investigation.

[3] 15 U.S.C. § 1125(a)(1)(B).

[4] 21 U.S.C. § 337(a).

[5] *POM Wonderful LLC v. Coca-Cola Co.*, 679 F.3d 1170, 1175-76, 2012 BL 122698, 102 U.S.P.Q.2d 1781 (9th Cir. 2012) (84 PTCJ 141, 5/25/12), *cert. granted*, 134 S. Ct. 895, 2014 BL 7267 (2014) (87 PTCJ 552, 1/17/14); *see* Part II.C.2, *infra*.

Lanham Act and the FFDCA.[6] We provide an overview of the framework through which courts view such cases, categorize these cases based on the types of advertising claims involved and describe the key implications from the case law for each category of advertising claim. Ultimately, this article proposes that, although many of these holdings appear inconsistent, they may nonetheless be synthesized, with certain exceptions.

Part I of this article describes the FFDCA and the Lanham Act and how these two statutes frequently come into conflict. Part II describes arguments raised by defendants in Lanham Act cases that false advertising claims involving FDA-regulated products are precluded or fall within FDA's primary jurisdiction. It also explains how courts have addressed these arguments generally. Part III examines particular Lanham Act cases involving FDA-regulated products and provides key principles and takeaways for six common types of advertising claims: (1) marketing authorization claims, (2) regulatory classification and status claims, (3) efficacy claims, (4) safety claims, (5) product attribute and composition claims and (6) drug equivalency-related claims.

I. Statutory Overview

To understand the legal complexity of false advertising cases involving FDA-regulated products, one must first understand both the FFDCA and the Lanham Act. This Part describes each statute and then explains how these statutes come into conflict in Lanham Act cases involving FDA-regulated products.

A. *Federal Food, Drug, and Cosmetic Act*

The FFDCA authorizes the FDA to regulate the marketing of foods, drugs, devices, cosmetics, dietary supplements, and tobacco products.[7] The purpose of the FFDCA is to protect consumers and the public health and ensure the safety of FDA-regulated products.[8]

The FFDCA prohibits, among other things, false or misleading statements in the labeling of regulated products.[9] The FFDCA defines the term ''labeling'' very broadly to include any material physically upon a product or its containers or accompanying the product.[10] The FDA also regulates the ''advertising'' of prescription drugs and restricted devices,[11] but the Federal Trade Commission (FTC) primarily regulates advertising for food, cosmetics, over-the-counter (OTC) drugs, and nonrestricted devices.[12]

No private right of action exists under the FFDCA.[13] Instead, only the government is authorized to enforce the FFDCA and file suit for noncompliance.[14] If a private firm believes that a competitor is violating the FFDCA, it can file an informal trade complaint[15] or formal citizen petition[16] with FDA. However, even if a trade complaint or citizen petition is well-founded, FDA may not necessarily act and initiate enforcement action against the alleged violator of the FFDCA. FDA ultimately has broad discretion to refuse to initiate enforcement actions.[17] Consequently, the private firm may consider alternative self-help remedies, such as the Lanham Act.

B. *Lanham Act*

Competitors frequently rely on the Lanham Act to obtain relief against unfair competition and false advertising. Section 43(a) of the Lanham Act prohibits false or misleading descriptions or representations of fact ''in commercial advertising or promotion'' concerning ''the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities.''[18] Section 43(a) was originally enacted in 1946 and then amended in 1988 to make the statute clearer with regard to false advertising claims.[19]

Section 43(a) is not self-enforcing; that is, no government agency directly enforces the false advertising provisions of the Lanham Act.[20] Rather, Section 43(a) was enacted to create a remedy precisely because the government lacks the capacity to police all commercial advertising; it implicitly recognizes that competitors can

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[6] Similar issues also arise for claims under state unfair competition and consumer protection statutes that involve FDA-regulated products. *See, e.g., Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 2013 BL 358318, 109 U.S.P.Q.2d 1154 (Fed. Cir. 2013) (87 PTCJ 435, 1/3/14). The intersection of these state laws with the FFDCA is beyond the scope of this article.

[7] 21 U.S.C. § 301 *et seq.*

[8] *See Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139, 28 U.S.P.Q.2d 1533 (4th Cir. 1993) (citing *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230 (3d Cir. 1990)).

[9] 21 U.S.C. §§ 343(a)(1) (foods), 352(a) (drugs and devices), 362(a) (cosmetics), 387c(a)(1) (tobacco products).

[10] 21 U.S.C. § 321(m); *see also* 21 C.F.R. § 202.1(l)(2).

[11] Restricted devices are those for which FDA has limited the sale, distribution or use only upon the authorization of a licensed practitioner or upon other conditions prescribed by FDA. 21 U.S.C. § 360j(e); 21 C.F.R. § 807.3(i). Most class III devices are restricted as a condition of approval, as are hearing aids and analyte specific reagents. *See* 21 C.F.R. §§ 801.420, 801.421 (hearing aids); 21 C.F.R. § 809.30 (analyte specific reagents).

[12] *See* FTC-FDA Memorandum of Understanding, 36 Fed. Reg. 18,539, 18,539 (Sept. 16, 1971) (''With the exception of prescription drugs, the Federal Trade Commission has primary responsibility with respect to the regulation of the truth or falsity of all advertising (other than labeling) of foods, drugs, devices, and cosmetics.''); 21 U.S.C. § 352(q) (describing false or misleading advertising for a restricted device as ''misbranding'' under the FFDCA).

[13] 21 U.S.C. § 337(a) (''[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.''). No private right of action exists under the FTC Act either. *See generally Holloway v. Bristol-Myers Corp.*, 485 F.2d 986 (D.C. Cir. 1973).

[14] *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001).

[15] *See* Thomas J. McGrew & Donald O. Beers, *When the FDA Takes No Action Against Violations of the Federal Food, Drug and Cosmetic Act, Can a Private Cause of Action Be Brought Under Section 43(a) of the Lanham Act?*, 47 Food & Drug L.J. 1, 1 (1992) (''In all cases of an FDCA violation, the indicated first step is a complaint to the . . . FDA.'').

[16] *See* 21 C.F.R. § 10.30.

[17] *See Heckler v. Chaney*, 470 U.S. 821, 837-38 (1985).

[18] 15 U.S.C. § 1125(a)(1)(B).

[19] Trademark Law Revision Act, Pub. L. No. 100-667, § 132, 102 Stat. 3935 (1988) (codified at 15 U.S.C. § 1125(a)). The revision amended the statute to cover both ''false or misleading'' statements, rather than just ''false'' statements. *Id.* The revision also clarified that the statute prohibits statements about either a plaintiff's or a defendant's products, rather than just a defendant's products. *Id.*

[20] Contrast the Lanham Act with the Federal Trade Commission Act, which also prohibits unfair and deceptive practices and which vests enforcement authority in the Federal Trade Commission.

  PTCJ ISSN 0148-7965

be highly effective in playing that enforcement role vis-à-vis each other.[21] Specifically, the Lanham Act was enacted ''to protect persons engaged in . . . commerce against unfair *competition*.''[22]

To establish a false advertising claim under the Lanham Act, the plaintiff must prove the following elements:

(1) the defendant has made a false or misleading statement;

(2) the false or misleading statement has actually deceived or has the capacity to deceive a substantial portion of the intended audience;

(3) the deception is material, in that it is likely to influence purchasing decisions;

(4) the advertised goods or the false statement entered interstate commerce; and

(5) the plaintiff has been injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with its products.[23]

The Lanham Act and the FFDCA potentially intersect when a plaintiff attempts to establish the first element. A Lanham Act plaintiff may attempt to use an FFDCA violation to support a claim that a statement is false or misleading; conversely, a Lanham Act defendant may attempt to use compliance with the FFDCA to show that a statement is not false or misleading. A plaintiff must show either that the challenged statement is ''literally false'' or ''false by necessary implication'' or that the statement is likely to mislead or confuse customers.[24] If a plaintiff establishes a statement is literally false or false by necessary implication, consumer deception is presumed.[25]

One of the primary benefits for companies pursuing Lanham Act litigation is the broad range of potential remedies, including both injunctive and monetary relief.[26] Injunctive relief can require the defendant to cease further distribution of the challenged advertising, engage in corrective advertising, or both.[27] Depending on the circumstances, monetary damages may include the plaintiff's lost profits and loss of goodwill, the defendant's profits (disgorgement), the cost of corrective advertising initiated by the plaintiff, court costs, and reasonable attorneys' fees.[28] A court also has discretion to treble the plaintiff's lost profits and loss of goodwill.[29]

C. *Tension Between the Lanham Act and the FFDCA*

The Lanham Act and the FFDCA intersect when a competitor brings a Section 43(a) false advertising claim involving an FDA-regulated product. As explained above, false or misleading statements in labeling and advertising can violate both the Lanham Act and the FFDCA. Yet the Lanham Act can only be enforced privately, and the FFDCA can only be enforced by the government. The statutes also serve different purposes. While the Lanham Act is primarily concerned with the truth or falsity of advertising claims to protect commercial interests, the FFDCA is primarily concerned with protecting the public interest in the safety and efficacy of FDA-regulated products.[30] The Lanham Act does not directly protect the public from false advertising or protect the public's interest in health and safety.[31] Rather, in enacting the Lanham Act, Congress implicitly determined that one means to protect consumers from false advertising was to provide a private right of action for competitors.[32]

In Lanham Act cases involving FDA-regulated products, courts have struggled for more than two decades with how to balance the competing objectives of the two statutes.[33] Courts theoretically could have taken the approach that no Lanham Act false advertising claims involving FDA-regulated products are permitted. Under this approach, only the government would have the ability to police false or misleading statements in the labeling and advertising of FDA-regulated products. Private entities seeking to stop deceptive actions of competitors would have to rely entirely on the discretion of the government in choosing to take enforcement action. On the other hand, courts could have determined that all Lanham Act claims involving FDA-regulated products are permitted.

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[21] The issue of standing under the Lanham Act and what entities may bring a false advertising claim was recently addressed by the Supreme Court. *See Lexmark Int'l, Inc. v. Static Control Components, Inc.*, No. 12-873, 2014 BL 80718, 109 U.S.P.Q.2d 2061 (U.S. 2014) (87 PTCJ 1223, 3/28/14).

[22] 15 U.S.C. § 1127 (emphasis added).

[23] *Merck Eprova AG v. Brookstone Pharms., LLC*, 920 F. Supp. 2d 404, 416. 2013 BL 24892 (S.D.N.Y. 2013); *see, e.g., Jarrow Formulas, Inc. v. Nutrition Now, Inc.*, 304 F.3d 829, 835 n.4, 63 U.S.P.Q.2d 1076 (9th Cir. 2002) (64 PTCJ 154, 6/14/02); *Warner-Lambert Co. v. Breathasure, Inc.*, 204 F.3d 87, 91-92, 53 U.S.P.Q.2d 1727 (3d Cir. 2000) (59 PTCJ 577, 2/18/00).

[24] *E.g., Merck Eprova*, 920 F. Supp. 2d at 417; Minutes of In Chambers – Court Order, *Mut. Pharm. Co. v. Watson Pharms., Inc.*, No. CV 09-5700 PA (RCx) (C.D. Cal. Oct. 19, 2009), ECF No. 139.

[25] *Merck Eprova*, 920 F. Supp. 2d at 417.

[26] *See* 15 U.S.C. §§ 1116-17.

[27] *See, e.g., Rhone-Poulenc Rorer Pharms., Inc. v. Marion Merrell Dow, Inc.*, 93 F.3d 511, 514, 516, 39 U.S.P.Q.2d 1832 (8th Cir. 1996).

[28] *See* 15 U.S.C. § 1117(a).

[29] 15 U.S.C. § 1117(a).

[30] *See Sandoz Pharms.*, 902 F.2d at 230.

[31] *See id.*; *Am. Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 145, 5 U.S.P.Q.2d 1571 (S.D.N.Y. 1987) (*quoting Am. Home Prods. Corp. v. Johnson & Johnson*, 436 F. Supp. 785, 797, 196 U.S.P.Q. 484 (S.D.N.Y. 1977), *aff'd*, 577 F.2d 160, 198 U.S.P.Q. 132 (2d Cir. 1978)).

[32] *See Serbin v. Ziebart Int'l Corp.*, 11 F.3d 1163, 1178-79, 28 U.S.P.Q.2d 1881 (3d Cir. 1993) (recognizing the Lanham Act as a ''commitment of institutional resources to the cause of consumers injured by false advertising'' but noting that nothing in the legislative history clearly demonstrates that consumers should have standing to sue under the Lanham Act).

[33] *See, e.g., POM Wonderful*, 679 F.3d at 1175 (''As sometimes happens with two broad federal statutes, the Lanham Act and the FDCA can conflict with each other. When faced with a potential conflict, courts try to give as much effect to both statutes as possible.'' (internal quotations omitted)); *Solvay Pharms., Inc. v. Ethex Corp.*, No. 03-2836 (JRT/FLN), 2004 BL 4082, at *3 (D. Minn. Mar. 30, 2004) (''Courts have recognized the potential conflict between the two Acts and have struggled to define the proper scope of each law.''); McGrew & Beers, *supra* note 15, at 2 (1992 law review article arguing that ''a private remedy under section 43(a) of the Lanham Act may be available to a firm whose competitor's marketing is in violation of the FDCA, even if the FDA is unwilling to take action.'').

Yet the courts did not adopt either of these black-and-white approaches. Thus, as one district court held in 1996, ''a plaintiff may bring a Lanham Act cause of action for affirmatively misrepresenting facts, even if the truth of those facts may be governed by FDA regulations.''[34] At the same time, courts have sought to prevent competitors from ''circumvent[ing] the FDA's exclusive enforcement authority.''[35] As a consequence, courts have had to determine on a largely case-by-case basis whether a particular Lanham Act claim involving an FDA-regulated product is ''precluded'' by the FFDCA or otherwise falls within FDA's primary jurisdiction.

II. A Defendant's Arguments: FFDCA Preclusion and FDA's Primary Jurisdiction

Due to the conflicts that arise between the Lanham Act and the FFDCA, defendants in Lanham Act lawsuits frequently move for dismissal, summary judgment, or both on the grounds that a particular claim is precluded[36] (or barred) by the FFDCA or falls within FDA's primary jurisdiction.[37] These two arguments are closely related, if not overlapping entirely, so courts typically view cases through one lens or the other. This Part provides an overview of these two arguments and highlights the apparent technical differences between them, although as a practical matter, the two arguments rarely point to different outcomes. This Part also provides two case examples to illustrate how these arguments have been applied in two key cases—*Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.*[38] and *POM Wonderful LLC v. Coca-Cola Co.*, the latter of which is now pending before the Supreme Court.[39]

A. *FFDCA ''Preclusion''*

The preclusion argument in Lanham Act cases is similar to a preemption defense, with the key difference being that the Lanham Act is a federal, rather than state, law. Indeed, the Solicitor General in an amicus brief arguing against certiorari in *POM Wonderful LLC v. Coca-Cola Co.* recognized that federal-state preemption principles are ''useful guides'' in analyzing the interaction of the FFDCA and the Lanham Act.[40] The analyses of several courts, in fact, actually use the term ''preemption'' to describe this argument,[41] although for purposes of this article, the term ''preclusion'' will be used. A defendant argues that a Lanham Act claim cannot proceed because of the FFDCA's broad regulation and the exclusive enforcement authority vested by Congress in the FDA.[42] Essentially, the defendant asserts that in resolving the conflict between the two statutes, the court should find that the FFDCA trumps the Lanham Act.

But as previously discussed in Part I.C, not all Lanham Act claims involving FDA-regulated products are barred. So courts must grapple with the difficult question of which false advertising claims are precluded and which claims are permitted. In *POM Wonderful LLC v. Coca-Cola Co.*, the U.S. Court of Appeals for the Ninth Circuit provided two over-arching principles for when Lanham Act false advertising claims are precluded:

''A plaintiff may not . . . sue under the Lanham Act to enforce the [F]FDCA or its regulations because allowing such a suit would undermine Congress's decision to limit enforcement of the [F]FDCA to the federal government. . . . Nor may a plaintiff maintain a Lanham Act claim that would require a court originally to interpret ambiguous FDA regulations, because rendering such an interpretation would usurp the FDA's interpretive authority.''[43]

Because of the first principle, a plaintiff cannot use a Lanham Act lawsuit to litigate an alleged violation of the FFDCA, in particular when FDA has not determined such a violation exists.[44] Under the second principle, a court should not originally interpret the FFDCA or FDA regulations because that task is solely FDA's responsibility. This second principle is related to the doctrine of primary jurisdiction, discussed further below, although courts do not always refer to it as such.[45]

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[34] *Summit Tech., Inc. v. High-Line Med. Instruments, Co.*, 922 F. Supp. 299, 307 (C.D. Cal. 1996) *(Summit I)*; *see* Mem. & Order at 10, *Braintree Labs., Inc. v. Nephro-Tech, Inc.*, No. 96-2459-JWL (D. Kan. Feb. 26, 1997).

[35] *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 928, 2010 BL 82307, 94 U.S.P.Q.2d 1617 (9th Cir. 2010) (79 PTCJ 796, 4/23/10).

[36] *E.g.*, Mem. & Order at 5, *Merck Eprova AG v. Brookstone Pharms. LLC*, No. 09 Civ. 9684 (RJS) (S.D.N.Y. Mar. 17, 2011), ECF No. 92 (''Defendant also argues that it is entitled to summary judgment on all of Plaintiff's claims because Plaintiff's claims are precluded by the [FFDCA].''); *Ferring Pharms., Inc. v River's Edge Pharms., LLC*, No. AW-09-02601, 2010 BL 181718, at *3 (D. Md. Aug. 6, 2010) (''River's Edge contends that the Plaintiff's Lanham Act claim is precluded by the [FFDCA]''). Not all cases use the exact ''preclusion'' language, but the argument in each case is fundamentally the same. *See POM Wonderful*, 679 F.3d at 1175-76 (''On appeal, POM contends that the district court erred in its holdings that the [FFDCA] bars its Lanham Act claim . . . .'').

[37] *E.g.*, *Mut. Pharm. Co., Inc. v. Watson Pharms., Inc.*, No. 09-5421 (GEB), 2010 BL 26027, at *3 (D.N.J. Feb. 8, 2010) (''Defendants filed a motion to dismiss plaintiffs' complaint, arguing that plaintiffs' claims are within the FDA's primary jurisdiction and amount to an impermissible private right of action under the [FFDCA].''); *Wyeth v. Sun Pharm. Indus., Ltd.*, No. 09-11726, 2010 BL 45158, at *3 (E.D. Mich. Mar. 2, 2010) (''Defendants challenge Plaintiff's complaint on the grounds that . . . exclusive jurisdiction for Plaintiff's claim rests with the FDA. . . .'')

[38] *Sandoz Pharms.*, 902 F.2d 222.

[39] *POM Wonderful*, 679 F.3d 1170.

[40] Br. for the United States as Amicus Curiae at 10, *POM Wonderful LLC v. Coca-Cola Co.*, No. 12-761 (U.S. Nov. 27, 2013).

[41] *See Schwarz Pharma, Inc. v. Breckenridge Pharm., Inc.*, 388 F. Supp. 2d 967, 972-74 (E.D. Wis. 2005); *Solvay Pharms., Inc. v. Global Pharms.*, 298 F. Supp. 2d 880, 883-84 (D. Minn. 2004).

[42] *See, e.g.*, *PhotoMedex*, 601 F.3d at 928 (9th Cir. 2010) (''[Plaintiff] is not permitted to circumvent the FDA's exclusive enforcement authority . . . .''); *Mylan*, 7 F.3d at 1139 (holding that a plaintiff may not ''use the Lanham Act as a vehicle by which to enforce the [FFDCA]'').

[43] *POM Wonderful*, 679 F.3d at 1175-76.

[44] *E.g.*, *PhotoMedex*, 601 F.3d at 928 (holding that the plaintiff is not permitted to circumvent FDA's authority to prove that the defendants violated the FFDCA ''when the FDA did not reach that conclusion''); Mem. & Order at 14, *Braintree Labs., Inc. v. Nephro-Tech, Inc.*, No. 96-2459-JWL (D. Kan. Feb. 26, 1997) (holding that the defendant's allegedly false advertising of its product as a ''dietary supplement'' was a ''classic misbranding claim[]'' for resolution by the FDA).

[45] *See, e.g.*, *Sandoz Pharms.*, 902 F.2d at 231 (holding that the plaintiff's claim would require the court to ''usurp administrative agencies' responsibility for interpreting and enforcing potentially ambiguous regulations.'').

  PTCJ ISSN 0148-7965

In determining which Lanham Act claims are permitted, several district courts have relied on the following additional principle:

''If the allegedly false or misleading nature of a statement can be *easily verified*, then the fact that the determination of the truth of that statement was made by the FDA is immaterial so long as the party can also show the other requirements for establishing a Lanham Act claim . . . .''[46]

For example, as discussed further in Part III.A.1, an express, false statement asserting FDA approval of a product is actionable under the Lanham Act.[47] The truth or falsity of such a statement—whether or not a product has actually received FDA approval—can be easily verified through a review of FDA approval databases or prior FDA correspondence relating to the product. No interpretation of the FFDCA or FDA regulations is required.

Where a Lanham Act false advertising claim is precluded, a plaintiff is frequently left without any effective means to challenge a competitor's marketing that is false and in violation of the law. The plaintiff's only option may be to attempt to convince FDA to take direct action against the competitor, although frequently a plaintiff will have already complained unsuccessfully to the FDA.[48]

B. *FDA's Primary Jurisdiction*

Under the primary jurisdiction doctrine, a defendant argues that the court should defer to the FDA on an issue that has been placed within its jurisdiction and that requires special expertise or uniformity in administration.[49] A Lanham Act claim that requires original interpretation of ambiguous FDA regulations would be one such example where the primary jurisdiction doctrine may be applicable.[50] In such a case, the FDA is in a better position than a court to interpret its own regulations and ensure that the regulations are administered in a uniform manner.[51] In an amicus brief in *POM Wonderful*, the Solicitor General recognized that these considerations in Lanham Act cases ''*mirror* those underlying the doctrine of primary jurisdiction'' and are ''primary-jurisdiction-like,'' although the Solicitor General was reluctant to describe these types of cases as true applications of primary jurisdiction.[52]

In discussing the primary jurisdiction doctrine in other contexts, the Supreme Court has explained:

'' '[P]rimary jurisdiction' . . . applies where a claim is originally cognizable in the courts, and comes into play whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body; in such a case the judicial process is suspended pending referral of such issues to the administrative body for its views.''[53]

The doctrine is designed to promote ''proper relationships between the courts and administrative agencies charged with particular regulatory duties.''[54] Primary jurisdiction is a *prudential* doctrine.[55] That is, in the limited circumstances when the primary jurisdiction doctrine is applicable, a court technically has the option to stay the case pending administrative action or dismiss the case without prejudice.[56] Accordingly, one technical difference between the preclusion argument discussed earlier and a primary jurisdiction argument is that the primary jurisdiction doctrine, even if applicable, does not mandate dismissal of a case. A court could stay the case, wait for FDA to decide the question at issue, and then proceed with the adjudication of the Lanham Act claim once FDA has provided its input.

Plaintiffs frequently bring Lanham Act cases challenging the false advertising or labeling of a competitor's products precisely because FDA has declined to take action against a competitor or offer a definitive interpretation of its regulations.[57] Thus, if a court applies the primary jurisdiction doctrine and refuses to take action pending input from FDA, the plaintiff in such a case is stuck between a rock and a hard place. The plaintiff has been unable to convince FDA to enforce the FFDCA directly against a competitor, and the plaintiff has been unable to convince a court to adjudicate the Lanham Act false advertising claim because the court wishes to defer to FDA's judgment.

C. *Seminal Case Examples*

Courts have addressed preclusion and primary jurisdiction arguments in Lanham Act cases involving FDA-regulated products for years. One of the first such cases—*Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.*[58]—was decided in 1990 by the Third Circuit and has been cited by nearly every subsequent case addressing these issues. More recently in 2012, the Ninth Circuit decided *POM Wonderful LLC v. Coca-Cola Co.*,[59] which broadened the circumstances under which FFDCA preclusion may be applicable.

1. Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.

In *Sandoz*, the labeling of the defendant's OTC cough syrup listed demulcents, topically acting antitussives, as

[46] *Hansen Beverage Co. v. Innovation Ventures, LLC*, No. 08-CV-1166-IEG (POR), 2009 BL 285318, at *5 (S.D. Cal. Dec. 23, 2009) (quoting *Mut. Pharm. Co. v. Ivax Pharms., Inc.*, 459 F. Supp. 2d 925, 935 (C.D. Cal. 2006)) (emphasis added).

[47] Mem. & Order at 12, *Braintree Labs., Inc. v. Nephro-Tech, Inc.*, No. 96-2459-JWL (D. Kan. Feb. 26, 1997); *see N. Am. Med. Corp., v. Axiom Worldwide, Inc.*, 522 F.3d 1211, 1225-26, 2008 BL 71066, 86 U.S.P.Q.2d 1462 (11th Cir. 2008) (75 PTCJ 626, 4/11/08).

[48] *See PhotoMedex* , 601 F.3d at 926, 930; *Sandoz*, 902 F.2d at 231 n.10.

[49] *See Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 938 (8th Cir. 2005); *Syntek Semiconductor Co. v. Microchip Tech., Inc.*, 307 F.3d 775, 781, 64 U.S.P.Q.2d 1149 (9th Cir. 2002) (64 PTCJ 391, 8/23/02).

[50] *See, e.g., Mut. Pharm. Co., Inc. v. Watson Pharms., Inc.*, No. 09-5421 (GEB), 2010 BL 26027, at *5 (D.N.J. Feb. 8, 2010).

[51] *See Summit Tech., Inc. v. High-Line Med. Instruments, Co.*, 933 F. Supp. 918, 934 (C.D. Cal. 1996) *(Summit II)*.

[52] Br. for the United States as Amicus Curiae Supp. Neither Party at 27, *POM Wonderful LLC v. Coca-Cola Co.*, No. 12-761 (U.S. Mar. 3, 2014) (87 PTCJ 1086, 3/14/14).

[53] *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 63-64 (1956) (citing *Gen. Am. Tank Car Corp. v. El Dorado Terminal Co.*, 308 U.S. 422, 433 (1940)).

[54] *Id.* at 63.

[55] *E.g., Clark v. Time Warner Cable*, 523 F.3d 1110, 1114, 2008 BL 91090 (9th Cir. 2008).

[56] *Reiter v. Cooper*, 507 U.S. 258, 268-69 (1993); *W. Pac. R.R.*, 352 U.S. at 63-64; *Clark*, 523 F.3d at 1114.

[57] *See PhotoMedex*, 601 F.3d at 926, 930; *Sandoz Pharms*, 902 F.2d at 231 n.10.

[58] *Sandoz*, 902 F.2d at 222.

[59] *POM Wonderful*, 679 F.3d 1170.

''inactive'' ingredients, yet the defendant advertised its cough syrup as working immediately after swallowing due to these demulcent ingredients.[60] Therefore, the plaintiff alleged that that the demulcents should be listed as ''active'' ingredients, based on existing FDA regulations, and that the defendant's labeling was false or misleading in violation of the Lanham Act.[61] In rejecting the claim, the court relied on the fact that FDA had not conclusively determined in its OTC monograph rulemakings whether demulcents should be labeled as active or inactive ingredients.[62] Accordingly, the court held that FDA ''should be given the first chance to exercise [its] discretion or to apply [its] expertise.''[63] Moreover, the court emphasized that it was not ''appropriate for a court in a Lanham Act case to determine preemptively how a federal administrative agency will interpret and enforce its own regulations.''[64] *Sandoz* is significant because it was the first major case to apply the principles of preclusion and primary jurisdiction (although it did not use these specific terms) to Lanham Act claims involving FDA-regulated products.

2. POM Wonderful LLC v. Coca-Cola Co.

In *POM Wonderful*, a manufacturer of pomegranate juice beverages argued that the name and labeling of competitor Coca-Cola's juice were false or misleading under the Lanham Act.[65] Coca-Cola's juice was named ''Pomegranate Blueberry,'' yet it contained 99.4 percent apple and grape juices and only 0.3 percent pomegranate juice and 0.2 percent blueberry juice.[66] POM Wonderful contended that the name of the juice misled consumers into believing that it contained primarily pomegranate and blueberry juices.[67] In addressing the plaintiff's claim, the Ninth Circuit recognized that FDA regulations permitted a beverage to bear the name of a juice that is not predominant by volume.[68] Accordingly, the court held that POM Wonderful's claim based on the name of the juice was precluded because ''FDA regulations authorize the name Coca-Cola has chosen.''[69] Thus, for the Lanham Act claim to succeed, the court would have had to ''undermine the FDA's apparent determination that so naming the product is not misleading.''[70] Interestingly, the court went out of its way to note that it did *not* find Coca-Cola's label was not deceptive.[71] The court's holding focused instead on the fact that Coca-Cola's label ''presumptively complies with the relevant FDA regulations'' and should not be disturbed.[72] Although this statement suggests that a defendant's compliance with the FFDCA acts as a defense to a Lanham Act claim or at least a safe harbor from liability, the court cautioned that mere compliance with the FFDCA or FDA regulations will not generally shield a defendant from Lanham Act liability.[73]

In both *Sandoz* and *POM Wonderful*, the unsuccessful plaintiffs were unable to use the Lanham Act as a means to remedy the allegedly deceptive actions of their competitors. According to the courts, their only potential recourse was to seek direct action by the FDA.[74]

POM Wonderful, however, is currently taking one last bite at the Lanham Act apple in the Supreme Court, which granted POM Wonderful's petition for certiorari in January 2014.[75] The Supreme Court is scheduled to hear oral argument on April 21, 2014, and a decision is expected in June. Amicus briefs from, among others, the Solicitor General (technically supporting neither party), several state attorneys general (supporting POM Wonderful), a former FDA Commissioner (supporting POM Wonderful), and the Generic Pharmaceutical Association (GPhA) (technically supporting neither party) are instructive for how they frame the interaction of the Lanham Act and the FFDCA.

The Solicitor General argues that POM Wonderful's Lanham Act claim ''is precluded only to the extent the [F]FDCA or FDA regulations specifically require or authorize the challenged aspects'' of the defendant's juice label.[76] According to the Solicitor General, because FDA regulations specifically permit Coca-Cola to name its juice in the manner it has, POM Wonderful's Lanham Act claim should be precluded insofar as it challenges the particular name of the juice.[77] However, the Solicitor General believes that POM Wonderful's other Lanham Act claims not directly addressed by the FFDCA or FDA regulations, such as the presentation of the name on the label, are not necessarily precluded.[78] The Solicitor General argues that FDA's mere ability to regulate juice labeling should not create ''field'' preclusion of all Lanham Act claims.[79]

In contrast to the Solicitor General, the state attorneys general insist that the FFDCA and FDA regulations ''leave room for a Lanham Act claim challenging aspects of a label that are not mandatory,'' even if the challenged labeling is authorized by the FFDCA and FDA regulations.[80] Applying the principles of ''impossibility preemption,'' the state attorneys general find that ''[a] manufacturer can both comply with FDA's labeling requirements *and* refrain from misleading consumers in ways that create Lanham Act liability.''[81] Because the name used for Coca-Cola's juice is not *required* by FDA regulations, the state attorneys general conclude that

[60] *Sandoz*, 902 F.2d at 224-25.
[61] *Id.* at 225.
[62] *Id.* at 230.
[63] *Id.* at 231.
[64] *Id.*
[65] *POM Wonderful*, 679 F.3d at 1172-73.
[66] *Id.* at 1173.
[67] *Id.* at 1174.
[68] *Id.* at 1176-77 (citing 21 C.F.R. § 102.33(c), (d)).
[69] *Id.* at 1176.
[70] *Id.* at 1177.
[71] *Id.* at 1178.
[72] *Id.*
[73] *Id.*

[74] *See id.* (''If the FDA believes that [the defendant's label] misleads consumers, it can act.''); *Sandoz*, 902 F.2d at 231 n.10 (''Sandoz is free to petition the FDA to investigate these alleged labeling violations . . . . Sandoz represents that it has embarked upon this path already. The fact that it has been unable to get a quick response from the FDA, however, does not create a claim for Sandoz under the Lanham Act.'').
[75] *POM Wonderful*, 679 F.3d at 1175-76.
[76] Br. for the United States as Amicus Curiae Supp. Neither Party at 9, *POM Wonderful LLC v. Coca-Cola Co.*, No. 12-761 (U.S. Mar. 3, 2014).
[77] *Id.* at 9-10.
[78] *Id.* at 10.
[79] *Id.* at 10.
[80] Br. of Amici Curiae States of Alaska, Haw., Ind., Me., Mass., Mo., Nev., N.H., Ore., and Tenn. in Supp. of Pet'r at 2, *POM Wonderful LLC v. Coca-Cola Co.*, No. 12-761 (U.S. Mar. 3, 2014).
[81] *Id.* at 4.

  PTCJ ISSN 0148-7965

POM Wonderful's Lanham Act claim should not be precluded by the FFDCA.[82]

Similarly, former FDA Commissioner Dr. Donald Kennedy asserts that the FFDCA ''merely sets a 'floor' for regulation of labels on which other laws can build.'' Thus, Kennedy claims the defendant could have complied with both FDA labeling regulations and the Lanham Act's ban on false advertising.[83] Kennedy adds that the FDA lacks the resources to exercise exclusive responsibility for policing false food labels.[84]

GPhA emphasizes in its brief that the Lanham Act cannot be used to ''second-guess'' the FFDCA and stresses that the Supreme Court should take into consideration the significant differences in how FDA reviews labeling for foods and juices versus other regulated products and in how preemption applies to foods and juices versus other regulated products.[85] GPhA urges the Court to be precise in its holding because even if the Court finds that POM Wonderful's claim is not precluded, the same rationale would likely not apply under the regulatory regime for generic drugs.[86]

III. Key Principles of Analysis Based on the Type of Advertising Claim

Advertising claims challenged in Lanham Act cases involving FDA-regulated products generally fall into one or more of the following six categories: (1) marketing authorization claims, (2) equivalency-related claims, (3) regulatory classification claims, (4) efficacy claims, (5) safety claims, and (6) product attribute and composition claims. This Part provides key principles for Lanham Act lawsuits for each of these categories of advertising claims. The outcomes of these cases were largely dependent on the types of claims being challenged and the type of FDA-regulated product involved.

A. *Marketing Authorization Claims*

Manufacturers frequently make claims that their products are legally marketed or have received FDA ''approval'' or ''clearance,'' depending on the type of product. Such marketing authorization claims may be express or implied. An example of an express claim would be ''Drug X is FDA-approved to treat obesity.'' An example of a potential implied claim might be that ''Drug X is safe and effective'' because arguably, consumers might think a product can only be considered ''safe and effective'' if it is FDA-approved. Courts have distinguished between express and implied marketing authorization claims in determining which claims may be actionable under the Lanham Act. Courts have also distinguished between products that require pre-marketing approval or authorization by FDA and those that do not require pre-marketing authorization.

[82] *Id.* at 4.

[83] Br. of Former FDA Comm'r Dr. Donald Kennedy As Amicus Curiae Supp. Pet'r at 2, *POM Wonderful LLC v. Coca-Cola Co.*, No. 12-761 (U.S. Mar. 3, 2014).

[84] *Id.* at 7.

[85] Br. for the Generic Pharm. Ass'n as Amicus Curiae Supp. Neither Party at 3-4, *POM Wonderful LLC v. Coca-Cola Co.*, No. 12-761 (U.S. Mar. 3, 2014).

[86] *See id.* at 14-19.

1. *Express promotional claims of FDA approval when a product has not in fact received approval are generally actionable.*

Courts have generally found that a Lanham Act claim alleging that a product is falsely advertised as ''FDA-approved'' is not precluded and does not fall within FDA's primary jurisdiction when the product has not in fact received approval.[87] The question of whether a product has received approval for a given use does not require FDA's expertise because it can be resolved through a review of FDA correspondence and FDA's product approval databases.[88]

In *Alpharma, Inc. v. Pennfield Oil Co.*, an animal feed additive manufacturer sued a competitor alleging that the competitor was falsely advertising one of its additives as having received FDA approval for certain uses.[89] The Eighth Circuit determined that the primary jurisdiction doctrine was not applicable and saw no reason to stay or dismiss the case.[90] The court reasoned that the question of whether a product *has been* approved as safe and effective is ''much different'' from the question of whether a product *should* be approved as safe and effective, and only the second question requires FDA's expertise.[91]

Similarly, in *Putney, Inc. v. Pfizer, Inc.*, a district court held that a defendant's false representation that a drug approved for use in humans was also approved for use in animals was actionable under the Lanham Act.[92] The court agreed with *Alpharma* that ''consistency and uniformity of regulation by the FDA would not be jeopardized by judicial resolution of a case in which the issue is whether a party's drug has been approved by the FDA.''[93]

Lastly, in *North American Medical Corp. v. Axiom Worldwide, Inc.*, the Eleventh Circuit held that a defendant's advertising of a class II medical device as FDA-approved was literally false.[94] Under the FFDCA and its implementing regulations, class II devices are only eligible for ''clearance,'' rather than ''approval,'' by FDA.[95] Thus, the court held the defendant's advertising of its spinal traction device as ''approved'' by FDA was actionable under the Lanham Act.[96] This false advertising claim did not require the court to ''step into the FDA's shoes.''[97]

[87] *See N. Am. Med. Corp.*, 522 F.3d 1211; *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 938-39 (8th Cir. 2005); *Putney, Inc. v Pfizer, Inc.*, No. 07-108-P-H, 2007 BL 170656, at *5-7 (D. Me. Oct. 17, 2007).

[88] *Alpharma*, 411 F.3d at 938.

[89] *Id.* at 935-36

[90] *Id.* at 938-39.

[91] *Id.* at 939.

[92] *Putney*, 2007 BL 170656, at *7 (''The allegation of an affirmative misrepresentation [of approval] means that the claim is actionable under the Lanham Act.'')

[93] *Id.* at *5-6.

[94] *N. Am. Med. Corp.*, 522 F.3dat 1225-26.

[95] *See* 21 U.S.C. §§ 360c, 360e; 21 C.F.R. §§ 807.97, 814.1.

[96] *N. Amer. Med. Corp.*, 522 F.3d at 1225-26.

[97] *Id.* at 1226 n.15.

2. *Implied claims of FDA approval based on mere marketing of a product or on use of terms like ''generic'' or ''safe and effective'' are generally not actionable, but specific promotional claims that strongly imply FDA approval when product has not in fact received approval may be actionable.*

A party cannot sue under the Lanham Act simply because a competitor has failed to obtain necessary FDA approval or clearance for its product. Moreover, Lanham Act claims asserting that advertising falsely implies FDA approval have been largely unsuccessful, especially where the implication of approval is weak. A Lanham Act claim that a product is falsely advertised based merely on the unlawful marketing of the product without FDA approval, and the failure to disclose the lack of approval, is generally not permitted.[98] For example, in *Mylan Laboratories, Inc. v. Matkari*, the Fourth Circuit rejected the theory that ''the very *act* of placing a drug on the market'' falsely implies FDA approval. The court explained that permitting such a claim would permit a plaintiff to use the Lanham Act as a means to enforce the FFDCA.[99]

In other cases, plaintiffs have claimed that specific terms in a defendant's advertising falsely implied FDA approval. In *Eli Lilly & Co. v. Roussel Corp.*, the plaintiff sued a competitor that marketed a generic version of the plaintiff's antibiotic.[100] The plaintiff alleged that the defendant's use of the terms ''generic,'' ''alternatives to brand-name drug products'' and ''safe and effective'' in advertising falsely implied that the defendant's product had been approved by FDA without the use of fraud or misrepresentation.[101] The court rejected the plaintiff's argument because it relied on interpretations of the FFDCA and FDA regulations, such as the approval standards and application requirements for generic drugs.[102]

Likewise, in *Barr Laboratories, Inc. v. Quantum Pharmic, Inc.*, the plaintiff claimed that the defendant's advertising of its drug as ''generic'' and ''bioequivalent'' to plaintiff's drug falsely implied FDA approval.[103] The plaintiff did not argue that the defendant's drug was in fact not a generic of and bioequivalent to the plaintiff's drug.[104] Because the defendant's advertising did not use any words or phrases that ''positively'' suggested FDA approval, the court held this Lanham Act claim was not actionable.[105]

In contrast to the cases described above, where a defendant's advertising comes very close to ''a bald representation of FDA approval,'' courts have been more willing to permit a Lanham Act claim to proceed.[106] For instance, in *Summit Tech, Inc. v. High-Line Medical Instruments, Co.*, the defendant's press release stated that the FDA had granted '' 'conditional' approval'' to one manufacturer for certain lasers used in eye surgery, but the release did not mention that the lasers sold by the defendant were not covered by this approval.[107] The court held the press release could reasonably be construed as an affirmative misrepresentation under the Lanham Act, rather than a mere failure to disclose a lack of approval.[108] The level of specificity in the plaintiff's allegations helped distinguish this claim from the impermissible implied approval claim in *Mylan*.

Of course, the line between a permissible implied claim and an impermissible one is not always clear. For example, in *Mutual Pharmaceutical Co. v. Ivax Pharmaceuticals, Inc.*,[109] manufacturers of the only FDA-approved version of a drug sued manufacturers of unapproved versions of the drug.[110] The plaintiffs alleged that defendants' marketing of its unapproved drugs through certain drug dispensing databases and ''price lists'' falsely implied FDA approval.[111] The plaintiffs offered consumer surveys that showed pharmacists believed placement of a drug on a price list meant the drug was approved by FDA.[112] The *Ivax* court found that these surveys substantiated plaintiffs' assertion that the defendants' use of price lists conveyed a misleading impression of FDA approval.[113] The court distinguished *Mylan* because instead of challenging ''the simple act of defendants marketing a non-approved drug,'' the *Ivax* plaintiffs were challenging the defendants' use of a ''specialized marketing channel'' that implied FDA approval.[114]

Yet in a case involving the same plaintiffs and very similar facts a few years later, another judge in the same district court came to the opposite conclusion. In *Mutual Pharmaceutical Co. v. Watson Pharmaceuticals, Inc.*, the plaintiffs, just as in *Ivax*, alleged that the inclusion of defendants' unapproved products on price lists and drug ordering systems confused pharmacists into believing the products were approved by FDA.[115] The *Watson* court declined to ''view the Lanham Act's false advertising provisions as broadly as did the *Ivax* court'' and refused to grant the plaintiffs' motion for a preliminary injunction.[116] The *Watson* and *Ivax* cases illustrate how difficult Lanham Act cases can be to re-

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[98] *See Mylan*, 7 F.3d at 1139; *Summit I*, 922 F. Supp. 299, 306-07 (C.D. Cal. 1996).

[99] *Mylan*, 7 F.3d at 1139.

[100] *Eli Lilly & Co. v. Roussel Corp.*, 23 F. Supp. 2d 460, 467 (D.N.J. 1998).

[101] *Id.* at 477.

[102] *See id.*

[103] *Barr Labs., Inc. v. Quantum Pharmics, Inc.*, No. 90-CV-4406, slip op. at *10 (E.D.N.Y. Feb. 7, 1994).

[104] *Id.* at *11.

[105] *Id.*

[106] *See Summit II*, 933 F. Supp. at 936; *Cf. In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales Practices Litig.*, 701 F. Supp. 2d 356, 2010 BL 70171 (E.D.N.Y. 2010) (permitting state law false advertising claim to proceed where defendant's use of FDA-approved statements for individual OTC drug components falsely implied FDA-approval of OTC combination products).

[107] *Summit II*, 933 F. Supp. at 936.

[108] *Id.* (denying defendant's motion to dismiss for this claim).

[109] *Ivax*, 459 F. Supp. 2d 925.

[110] *See, e.g.*, *Ivax*, 459 F. Supp. 2d at 930-31.

[111] *Id.* at 931.

[112] *Id.* at 939.

[113] *Id.* at 942.

[114] *Id.*; *see also Mut. Pharm. Co., Inc. v. Watson Pharms., Inc.*, No. 09-5421 (GEB), 2010 BL 26027, at *5 (D.N.J. Feb. 8, 2010).

[115] Civil Minutes – General at 1, *Mut. Pharm. Co. v. Watson Pharms., Inc.*, No. CV 09-5700 PA (RCx) (C.D. Cal. Oct. 19, 2009), ECF No. 139. The plaintiffs even offered consumer surveys as evidence of the confusion. *Id.* at 2.

[116] *Id.* at 5 (''Even assuming that some portion of Defendants' marketing activities are not within the primary jurisdiction of the FDA, this Court still concludes that Plaintiffs have not established a likelihood of success on the merits.'').

  PTCJ ISSN 0148-7965

solve, as two judges on the same court could not even reach the same holding when faced with essentially the same facts.

3. *Promotional claims of marketing authorization for products that do not require FDA approval or clearance in the first instance, such as certain modified medical devices or drugs ''generally recognized as safe and effective,'' are likely not actionable.*

Not all FDA-regulated products, or versions of products, require pre-marketing authorization by FDA, and courts have been reluctant to permit Lanham Act claims relating to the approval of such products. For example, manufacturers of most class II (and some class I) devices must submit a 510(k) premarket notification to FDA before the initial marketing of such a device.[117] FDA will grant a ''clearance'' if it determines the device is ''substantially equivalent'' to a legally-marketed device not subject to premarket approval by FDA.[118] However, when a manufacturer modifies a previously-cleared device, the manufacturer may not have to submit a new 510(k) notification.[119] In such a case, the FDA has not affirmatively cleared the modified device. However, the manufacturer argues the modifications to the device did not trigger a new 510(k) notification because the modified device is still covered by the prior clearance.[120] If the manufacturer then advertises its modified device as ''FDA-cleared,'' determining the truth or falsity of this statement is a challenge.

When faced with this issue, the Ninth Circuit held that the plaintiff's Lanham Act claim was barred.[121] Because the FFDCA and FDA regulations ''place responsibility in the first instance on the manufacturer to determine whether its device is covered by a previous FDA clearance,'' the plaintiff could not establish that the defendant's modified dermatological laser had not been cleared when the FDA had not taken that position.[122] Despite the plaintiff's repeated complaints to FDA, the FDA never took any action that indicated the defendant's modified device lacked clearance.[123] In fact, the court suggested the plaintiff's unsuccessful outreach to FDA prior to filing its Lanham Act claim actually *supported* preclusion.[124] Accordingly, the court refused to permit the plaintiff to assume what it viewed as the exclusive enforcement authority vested in FDA by the FFDCA.[125]

Other FDA-regulated products that manufacturers claim do not require pre-marketing authorization by FDA include, among others, ''generally recognized as safe and effective'' (GRAS/E) drugs and ''grandfathered'' drugs. The FFDCA requires FDA approval of all ''new drugs.''[126] However, GRAS/E drugs and drugs marketed before enactment of the FFDCA in 1938 (*i.e.* ''grandfathered'' drugs) are specifically carved out of the definition of ''new drug.''[127]

In *Healthpoint, Ltd. v. Ethex Corp.*, two manufacturers of unapproved wound debridement ointments sued each other under the Lanham Act, each alleging, among other things, that the other made claims implying FDA approval of its drug.[128] Neither manufacturer had formally sought FDA approval, nor had FDA taken official action to remove either drug from the market.[129] Each manufacturer argued that its drug was lawfully marketed as either a GRAS/E or grandfathered drug.[130] The court held that the determination of whether both drugs were lawfully marketed was committed to the FDA.[131] Thus, these particular Lanham Act claims were precluded because their resolution would have required direct interpretation and application of the FFDCA.[132]

B. *Regulatory Classification and Status Claims*

Occasionally competitors argue over how a particular product should be classified according to the FFDCA. The distinctions between a ''drug'' and a ''dietary supplement'' and a ''dietary supplement'' and a conventional ''food'' are not always clear.[133] Yet these distinctions are significant because the regulatory requirements for each type of product are very different.

Promotional claims that allegedly mislead regarding the regulatory classification of a product (e.g., whether a product is a ''dietary supplement'' versus a ''food'' or ''drug'') are often not actionable. A Lanham Act claim asserting that a product is falsely advertised as a certain type of FDA-regulated product is often precluded because such claims require interpretation and application of definitions in the FFDCA.[134] For example, in *Hansen Beverage Co. v. Innovation Ventures, LLC*, an energy drink manufacturer brought a Lanham Act counterclaim alleging that the plaintiff's energy drink was falsely labeled as a dietary supplement yet promoted as a conventional food in violation of the FFDCA.[135] The court determined the counterclaim was precluded because it was ''a straightforward misbranding claim best resolved by FDA.''[136]

Similarly, in *Braintree Laboratories, Inc. v. Nephro-Tech, Inc.*, the defendant marketed a ''dietary supple-

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[117] *See* 21 U.S.C. §§ 360(k), 360c(B).

[118] *See* 21 C.F.R. § 360c(f)(1)(A); 21 C.F.R. § 807.100.

[119] A new 510(k) notification is only required if the device is ''significantly changed or modified in design, components, method of manufacture, or intended use.'' 21 C.F.R. § 807.81(a)(3).

[120] *See id.*

[121] *PhotoMedex*, 601 F.3d at 928.

[122] *Id.*

[123] *Id.* at 926, 930. FDA responded to each of plaintiff's complaints with the vague statement that ''we will evaluate this matter to determine what follow-up action is appropriate.'' *Id.* at 926.

[124] *Id.* at 930 (''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.'').

[125] *Id.* at 924-25, 930.

[126] 21 U.S.C. § 355(a).

[127] 21 U.S.C. § 321(p).

[128] *Healthpoint, Ltd. v. Ethex Corp.*, 273 F. Supp. 2d 817, 829-30 (W.D. Tex. 2001).

[129] *Id.* at 840.

[130] *See id.* at 839-41 & n.111.

[131] *Id.* at 841.

[132] *Id.*

[133] *See* 21 U.S.C. § 321(g) (drug), 321(ff) (dietary supplement), 321(f) (food).

[134] *Hansen Beverage Co. v. Innovation Ventures, LLC*, No. 08-CV-1166-IEG (POR), 2009 BL 285318, at *8 (S.D. Cal. Dec. 23, 2009); Mem. & Order at 16, *Braintree Labs., Inc. v. Nephro-Tech, Inc.*, No. 96-2459-JWL (D. Kan. Feb. 26, 1997).

[135] *Hansen*, 2009 BL 285318, at *8-9; *see* 21 U.S.C. § 321(ff) (defining ''dietary supplement'' to exclude products ''represented for use as a conventional food'').

[136] *Hansen*, 2009 BL 285318, at *9.

ment'' with the same active ingredient as the plaintiff's FDA-approved kidney disease drug.[137] The plaintiff alleged that the defendant's advertising of its product as a ''dietary supplement'' was false or misleading under the Lanham Act.[138] The plaintiff argued its claim was not precluded either because (1) the FFDCA definition only provided a standard that the defendant failed to meet and did not have to be interpreted by the court or (2) even in the absence of the FFDCA, the defendant's product was not a ''dietary supplement'' as the term is ordinarily understood.[139] Nevertheless, the court determined that the plaintiff's claim was a ''classic misbranding claim[]'' and held that interpretation of the term ''dietary supplement'' should be resolved solely by FDA.[140]

C. *Efficacy Claims*

Efficacy claims, particularly comparative claims, are frequent points of contention between competitors. If Company A believes its device is the only effective instrument for use in a particular surgical procedure, then Company B's promotion of its device as superior to Company A's device for the same use could force Company A to pursue remedies under the Lanham Act. Whether a particular promotional claim may be challenged under the Lanham Act depends in part on whether FDA has specifically authorized the claim.[141] If FDA has not definitively authorized or disapproved of the challenged claim, then a Lanham Act claim is usually permitted where the court would not have to interpret any FDA regulation.[142] Conversely, if FDA has authorized the challenged advertising or labeling claim, then a Lanham Act claim is unlikely to be successful, as discussed below.

1. *Efficacy claims, including superiority and compatibility claims, are not actionable where FDA has specifically authorized or approved the claims.*

A Lanham Act claim asserting that a product is falsely advertised as effective for a particular use is not actionable where FDA has specifically authorized the promotional claim as part of the clearance or approval process for the product. For example, in *Cytyc Corp. v. Neuromedical Systems, Inc.*, the challenged advertising implied that a manufacturer's class III cervical cancer detection device was superior to a conventional Pap smear.[143] As part of the approval process for the device, FDA had approved a number of labeling statements about the device's efficacy, including that the device was ''significantly more effective than the conventional Pap smear.''[144] Therefore, the court rejected the Lanham Act challenge because the manufacturer's advertising was ''consistent with the substantive claims approved by the FDA.''[145] Even though the challenged advertising statements did not ''correspond precisely'' to the FDA-approved labeling, they were similar enough for the court to conclude they were not false or misleading.[146] FDA's approval of the manufacturer's advertising effectively amounted to a defense against the Lanham Act claim.[147]

The court in *Rita Medical Systems, Inc. v. Resect Medical, Inc.* reached a similar conclusion with respect to a device manufacturer's claim that its ablation (surgical excision) device was compatible with a competitor's RF generator.[148] The competitor alleged as part of its Lanham Act claim that the use of the two devices together was untested and potentially unsafe.[149] Because the 510(k) notification for the FDA-cleared ablation device specifically stated that the ablation device was designed for use with the competitor's RF generator,[150] the court held that it could not review the truthfulness of the challenged advertising without converting the Lanham Act claim into a review of FDA's clearance decision.[151] Essentially, through its clearance of the defendant's device, FDA authorized the defendant to make the challenged compatibility claims, so the court could not undermine that decision in a Lanham Act case.

2. *Efficacy claims may be actionable where FDA has specifically objected to the claims.*

When FDA has expressly objected to a particular promotional claim, a Lanham Act suit alleging that this claim is false or misleading is usually not precluded, at least if there is no evidence FDA is considering formal enforcement action.[152] In fact, rather than acting as a barrier to a plaintiff's false advertising claim, FDA's objection to an efficacy claim can act as persuasive evidence of the falsity of the claim.[153]

In *Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, the FDA, in a series of letters, repeatedly rejected a drug manufacturer's promotional claims that its X-ray contrast media were superior to a competitor's.[154] The court permitted the competitor's Lanham Act claim challenging this same advertising to proceed because the claim did not require a preemptive determination of how FDA would interpret and enforce its regulations.[155] Rather, the numerous letters FDA had sent the manufacturer sufficiently informed the court of the

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[137] Mem. & Order at 2, *Braintree Labs., Inc. v. NephroTech, Inc.*, No. 96-2459-JWL (D. Kan. Feb. 26, 1997).
[138] *Id.* at 3-4.
[139] *Id.* at 13.
[140] *Id.*
[141] *See, e.g., Cytyc Corp. v. Neuromedical Sys., Inc.*, 12 F. Supp. 2d 296, 301 (S.D.N.Y. 1998).
[142] *See, e.g., Hansen Beverage Co. v. Innovation Ventures, LLC*, No. 08-CV-1166-IEG (POR), 2009 BL 285318 (S.D. Cal. Dec. 23, 2009).
[143] *Cytyc*, 12 F. Supp. 2d at 301.
[144] *Id.*
[145] *Id.*
[146] *Id.*
[147] *See id.*
[148] Order Den. Prelim. Inj. and Vacating Hr'g at 1, *Rita Med. Sys., Inc. v. Resect Med., Inc.*, No. C 05-03291 WHA, (N.D. Cal. July 17, 2006), ECF No. 165.
[149] *Id.*
[150] The 510(k) stated that the defendant's ablation device ''is designed for use with a standard FDA cleared RF generator'' and then cited the plaintiff's device specifically. *Id.* at 4-5 (internal quotations omitted).
[151] *Id.* at 6.
[152] *See Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 469-71, 475, 2009 BL 120840 (D.N.J. 2009); *Zeneca Inc. v. Eli Lilly & Co.*, No. 99 CIV. 1452 (JGK), 1999 BL 2806, at *1, 35 (S.D.N.Y. July 19, 1999).
[153] *Bracco*, 627 F. Supp. 2d at 471, 475; *Zeneca*, 1999 BL 2806, at *35.
[154] *Bracco*, 627 F. Supp. 2d at 411-12.
[155] *Id.* at 470.

  PTCJ ISSN 0148-7965

agency's position.[156] Although the defendant argued that the plaintiff was attempting ''to use the Lanham Act as a backdoor for private enforcement of the FFDCA,'' the court concluded that resolution of the plaintiff's claim would not ''usurp the FDA's authority or preempt its findings in an ongoing investigation.''[157] Because there was ''no indication of an ongoing dialogue'' between the defendant and FDA, there was no reason for the court to defer to the FDA.[158]

Similarly, in *Zeneca, Inc. v. Eli Lilly & Co.*, the plaintiff alleged that the defendant falsely advertised its drug as proven to reduce the risk of breast cancer, yet the FDA-approved labeling of the drug stated that its effectiveness ''in reducing the risk of breast cancer has not yet been established.''[159] The court found the defendant's advertising was literally false and relied on FDA's position reflected in the labeling statement as persuasive, although not determinative, evidence.[160]

3. *Off-label or unapproved efficacy claims are not automatically false or misleading.*

In recent years, government investigations have focused significant attention on off-label promotion by drug and device companies.[161] Off-label promotion occurs whenever a manufacturer promotes a product in a manner inconsistent with its FDA-cleared or FDA-approved labeling, such as for different indications or different patient populations.[162] Plaintiffs in Lanham Act lawsuits occasionally argue that a competitor's efficacy claim is false or misleading simply because it is off-label. Such off-label promotional claims are not automatically false or misleading.[163]

For instance, in *Nightingale Home Healthcare, Inc. v. Anodyne Therapy, LLC*, the plaintiff argued that the defendant falsely advertised its class III infrared lamp device as a treatment for peripheral neuropathy, an off-label use.[164] FDA had sent the defendant a warning letter objecting to the off-label promotion of the device for peripheral neuropathy and other conditions.[165] The plaintiff's Lanham Act claim failed because the mere fact that the defendant's advertising was off-label was insufficient to establish its falsity.[166] The court found that the FDA warning letter ''was not based on the dangerousness or ineffectiveness of the lamp'' for treating peripheral neuropathy, but was instead based merely on the fact that the defendant's marketing exceeded the scope of approval originally sought for the device in the premarketing approval application.[167]

The outcome of *Nightingale* can be reconciled with the *Bracco* and *Zeneca* cases discussed above because in *Nightingale*, FDA never specifically opined on the effectiveness of the off-label use being promoted. In contract, in *Bracco* and *Zeneca* where FDA's prior statements were considered persuasive evidence of falsity, FDA had previously raised specific objections to the scientific evidence offered to support the challenged off-label efficacy claims.[168]

4. *Efficacy claims for products that do not require FDA premarketing authorization are typically actionable where there is no relevant FDA regulation addressing the claims that a court would have to interpret.*

For products like foods, dietary supplements, and cosmetics that do not require FDA approval or clearance prior to marketing, a Lanham Act lawsuit asserting that an efficacy claim is false or misleading is often not precluded and does not fall within FDA's primary jurisdiction where no FDA regulation addresses the challenged claim.[169] For example, in *Hansen Beverage*, discussed above in Part III.B, the plaintiff alleged that the defendant falsely advertised its energy drink as ''twice the buzz'' of a regular energy drink.[170] The court held that this claim was not precluded because no FFDCA provision or FDA regulation specifically addressed energy drinks or the efficacy of such products.[171]

D. *Safety Claims*

Safety-related promotional claims take multiple forms. A manufacturer may affirmatively state that its product is safe for a particular use.[172] In addition, a competitor may allege the existence of an implied safety claim if the manufacturer's advertising fails to disclose risks associated with the product.[173] Defendants in Lanham Act cases involving safety claims often argue that such claims are the province of FDA and precluded by the FFDCA, given that one of FDA's primary functions is ensuring the safety of regulated products.

1. *Express or implied safety claims are typically not false or misleading where FDA has specifically authorized or approved the challenged claims.*

Just as efficacy claims are typically not considered false or misleading where FDA has authorized the

[156] *Id.*
[157] *Id.*
[158] *Id.* at 471.
[159] *Zeneca*, 1999 BL 2806, at *1.
[160] *Zeneca*, 1999 BL 2806, at *35.
[161] *See, e.g.*, John E. Osborn, *Can I Tell You The Truth? A Comparative Perspective On Regulating Off-Label Scientific And Medical Information*, 10 YALE J. HEALTH POL'Y L. & ETHICS 299, 301-03 (2010).
[162] *See United States v. Caronia*, 703 F.3d 149, 152-53, 2012 BL 316528 (2d Cir. 2012); Ralph F. Hall & Elizabeth S. Sobotka, *Inconsistent Government Policies: Why FDA Off-Label Regulations Cannot Survive First Amendment Review Under* Greater New Orleans, 62 FOOD & DRUG L.J. 1, 6 (2007).
[163] *See Nightingale Home Healthcare, Inc. v. Anodyne Therapy, LLC*, No. 1:06-cv-1435-SEB-JMS, 2008 BL 218125, at *5-7 (S.D. Ind. Sept. 18, 2008).
[164] *Id.* at *1, 5. The defendant's device was approved only ''for relief of minor muscle and joint pain and improvement of superficial circulation.'' *Id.* at *1 (internal quotations omitted).
[165] *Id.* at *2.
[166] *Id.* at *5.
[167] *Id.* at *6.
[168] *See Bracco*, 627 F. Supp. 2d at 469-71; *Zeneca*, 1999 BL 2806, at *35.
[169] *See, e.g.*, *Hansen Beverage Co. v. Innovation Ventures*, No. 08-CV-1166-IEG (POR), 2009 BL 285318, at *4 (S.D. Cal. Dec. 23, 2009) (''[A] Lanham Act claim requiring interpretation and enforcement of FDA regulations is not properly decided as an original matter by the district court.'').
[170] *Id.* at *16-17.
[171] *Id.* at *18.
[172] *See, e.g.*, *Am. Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 145 (S.D.N.Y. 1987) (label of defendant's OTC drug stated ''SAFE, FAST PAIN RELIEF'').
[173] *See, e.g.*, *Ivax*, 459 F. Supp. 2d at 936 (labeling of defendants' unapproved drug omits certain adverse drug interactions and warnings).

claims,[174] courts similarly are reluctant to find FDA-approved safety claims to be false or misleading.[175] For example, in *American Home Products Corp. v. Johnson & Johnson*, the plaintiff objected to an aspirin manufacturer describing its drug as ''safe'' in large letters on the front of packaging while placing a warning related to Reye Syndrome in the fine print on the back of the packaging.[176] The court declined to find that the safety message conveyed by the labeling was false or misleading.[177] Because FDA had approved the labeling of the defendant's drug, including the placement of the Reye Syndrome warning, through the OTC monograph process, the court held that any question related to the adequacy of the drug's warnings should be addressed by FDA rather than in a Lanham Act lawsuit.[178]

2. *Advertising or labeling that omits certain safety risks may be actionable if FDA has already determined that the omitted information is required for the specific product or category of product.*

A Lanham Act claim based on a manufacturer's failure to disclose certain safety risks in advertising is usually barred because a false advertising claim generally cannot be based on the failure to disclose a fact when that fact is being determined by FDA.[179] However, if FDA has already determined the disclosures required to ensure the safety of a product, then a Lanham Act claim based on a manufacturer's failure to provide these disclosures *may* be permitted.[180] Courts in *Ivax* and *Watson*, discussed earlier in Part III.A., faced this specific issue and came to conflicting results.

In *Ivax*, the manufacturer of the only FDA-approved version of quinine sulfate alleged that the labeling of identical, but unapproved, quinine sulfate products was false and misleading because it omitted specific safety information, including adverse drug interactions and warnings, that FDA had required in the labeling of the approved drug.[181] Because FDA had ''already determined'' the labeling required for the plaintiff's quinine sulfate product, the plaintiff alleged that the defendants' labeling, which failed to conform to these requirements, must be false and misleading.[182] The *Ivax* court held that the plaintiff's claim was not precluded because resolution would not require any original interpretation or application of the FFDCA or FDA regulations.[183]

Yet under nearly identical facts, the *Watson* court reasoned that ''disputes concerning the content of [competitors' drug] labels and inserts fall[] . . . squarely within the primary jurisdiction of the FDA.''[184] The conflicting results of *Ivax* and *Watson* suggest that potential Lanham Act plaintiffs should carefully consider how to frame safety-related claims so as to convince the court that FDA's expertise is not necessary for their resolution. Additionally, the *Ivax* and *Watson* cases do not address how courts analyze safety-related claims for foods, dietary supplements, and cosmetics, which are not as heavily regulated by FDA as prescription drugs.

E. *Product Attribute and Composition Claims*

Lanham Act lawsuits frequently challenge advertising claims related to the attributes or composition of a product, such as the identity or amount of certain ingredients,[185] the expiration date,[186] or the serving size.[187] The case law involving this category of advertising claim is the most difficult to generalize of the six categories discussed in this article. The holdings of these cases are also the most difficult to reconcile with each other. Like other Lanham Act cases involving FDA-regulated products, these cases generally turn on whether resolution of a particular Lanham Act claim would require original interpretation of FDA regulations or policies.[188] But how specific or on-point must the FDA statement be for preclusion to apply? In the absence of a specific, on-point FDA statement addressing the relevant issue, should the court permit the Lanham Act claim? Or conversely, should the court apply the primary jurisdiction doctrine and wait for FDA to speak on the issue? The resolution of these questions is a very fact-specific inquiry and can depend on the type of FDA-regulated product involved.

1. *A Lanham Act claim may be permitted even if the claim implicates the FFDCA or FDA regulations relating to product characteristics or identity, so long as the claim can be proven without referencing or undermining the FFDCA or FDA regulations.*

A Lanham Act claim is not necessarily precluded and does not fall within FDA's primary jurisdiction just be-

[174] *See supra* Part III.C.

[175] *Amer. Home Prods.*, 672 F. Supp. at 145 (''If FDA approval of the precise label used by a drug manufacturer is a defense to a consumer's product liability action, it should be, *a fortiori*, a defense to a competitor's action under the Lanham Act.'').

[176] *Id.* at 145. According to the plaintiff's allegations, children and teenagers with viral diseases who took aspirin-containing products incurred a risk of contracting Reye Syndrome, potentially fatal disease characterized by swelling of the brain and fatty degeneration of the liver. *Id.* at 136-37.

[177] *Id.* at 145.

[178] *Id.*. Additionally, on three occasions, FDA had reviewed the defendant's drug packages for compliance with the requirement to include a Reye Syndrome warning and never once questioned the defendant's compliance. *Id.* at 141.

[179] *See Summit I*, 922 F. Supp. at 307; *Cf. Aaronson v. Vital Pharms., Inc.*, No. 09-CV-1333 W (CAB), 2010 BL 32694, at *2-3 (S.D. Cal. Feb. 17, 2010) (applying primary jurisdiction doctrine to dismiss claim under state unfair competition statute based on manufacturer's alleged failure to disclose inherent safety risks associated with its energy drink).

[180] *Compare Ivax*, 459 F. Supp. 2d at 936-39, *with* Civil Minutes - General at 5, *Mut. Pharm. Co. v. Watson Pharms., Inc.*, No. CV 09-5700 PA (RCx) (C.D. Cal. Oct. 19, 2009), ECF No. 139.

[181] *Ivax*, 459 F. Supp. 2d at 936-37.

[182] *Id.* at 937, 939.

[183] *See id.* at 939 (also finding probability of success necessary to grant preliminary injunction).

[184] Minutes of In Chambers – Court Order at 5, *Mut. Pharm. Co. v. Watson Pharms., Inc.*, No. CV 09-5700 PA (RCx) (C.D. Cal. Oct. 19, 2009), ECF No. 139.

[185] *See, e.g., Grove Fresh Distribs., Inc. v. Flavor Fresh Foods, Inc.*, 720 F. Supp. 714 (N.D. Ill. 1989) (100 percent orange juice from concentrate) *(Grove Fresh I)*.

[186] *See Pamlab, LLC v. Macoven Pharms.*, 881 F. Supp. 2d 470, 472 (S.D.N.Y. 2012) (expiration date of dietary supplement).

[187] *See Hansen Beverage Co. v. Innovation Ventures, LLC*, No. 08-CV-1166-IEG (POR), 2009 BL 285318, at *7-8 (S.D. Cal. Dec. 23, 2009) (serving size of energy drink).

[188] *See, e.g., POM Wonderful*, 679 F.3d at 1176.

   ISSN 0148-7965

cause the plaintiff asserts that the defendant failed to comply with a particular FDA standard.[189] For instance, in *Grove Fresh Distributors, Inc. v. Flavor Fresh Foods, Inc. (Grove Fresh I)*, the plaintiff alleged that the defendant falsely represented their juice product as being ''100% orange juice from concentrate,'' even though the product contained various additives.[190] The defendant countered that the plaintiff was improperly attempting to privately enforce FDA's definition, established in a final regulation, of ''orange juice from concentrate.''[191] The court declined to dismiss the plaintiff's claim just because it relied on an FDA regulation.[192] Rather, the Lanham Act permits the use of the FFDCA and FDA regulations ''to establish the standard or duty which defendants allegedly failed to meet.''[193] Moreover, the court recognized that the plaintiff could establish a Lanham Act violation in the absence of any FDA regulation based on the market definition of ''orange juice from concentrate.''[194]

In a subsequent, related case (*Grove Fresh II*), the court reached the same outcome but with a slightly different rationale: the plaintiff ''cannot base its Lanham Act claim upon the violation of the FDCA'' but instead *must* rely on the market definition of orange juice from concentrate.[195] Because the FFDCA does not provide a private right of action, the *Grove Fresh II* court did not believe a Lanham Act claim could rely on the FFDCA to establish the standard the defendant failed to meet.[196] Additionally, the court indicated that if the market definition of the term turned out to be inconsistent with the FDA's definition, then the plaintiff's claim would be precluded.[197]

Due to their somewhat conflicting holdings, the *Grove Fresh* cases suggest that a Lanham Act claim should ideally strike a delicate balance by avoiding direct reliance on FDA regulations as the standard for falsity while simultaneously asserting that the standard for falsity is consistent with the same FDA regulations.

2. *Promotional claims that misrepresent the identity, ingredients and basic characteristics of a product may be actionable if a court does not have to originally interpret the FFDCA or FDA regulations.*

Promotional claims that misrepresent product characteristics usually may be challenged under the Lanham Act, so long as resolution of the false advertising claim would not require any original interpretation of FDA regulations. But where applicable FDA regulations exist and the challenged promotional claims comply with these regulations, then the Lanham Act claim is likely precluded under the rationale of *POM Wonderful*, discussed earlier in Part II.C.2.[198]

For example, in *Merck Eprova AG v. ProThera, Inc.*, a Lanham Act claim asserting that the main ingredient in the defendant's dietary supplement was mislabeled was not precluded because the court could evaluate the truthfulness of the labeling based solely on accepted standards in the scientific and dietary supplement community without any reliance on FDA regulations.[199] Indeed, the plaintiff did not allege the defendant had violated the FFDCA or any FDA regulations because no statutory or regulatory provisions specifically addressed the mislabeling about which the plaintiff complained.[200]

Similarly, in *Sirius Laboratories, Inc. v. Rising Pharmaceuticals, Inc.*, the plaintiff alleged that the defendant's drug was falsely labeled as ''Anthralin Cream 1 percent USP'' because it actually contained less than one percent anthralin, as defined by the United States Pharmacopeia (USP).[201] Because the USP and its standards exist independently of the FDA, the court recognized that the plaintiff's claim would not require interpretation of the FFDCA or any FDA regulations.[202] Accordingly, the court held the claim was not precluded and did not fall within FDA's primary jurisdiction.[203]

Even in cases where an FDA regulation is implicated, a court may still permit a Lanham Act claim if the regulation does not specifically address the alleged falsity in the defendant's advertising. In *Vermont Pure Holdings, Ltd. v. Nestle Waters North America Inc.*, the plaintiff alleged that the defendant falsely advertised the purity and source of its bottled water.[204] FDA had promulgated a final regulation establishing a standard of identity and quality for bottled water, including allowable levels of certain contaminants.[205] Nevertheless, the court determined the plaintiff's claim did not require interpretation or application of any FDA regulations because no federal standards of *purity* existed for bottled water.[206] The court noted that the FDA had refused to even define the term ''pure'' when it issued the bottled water regulation.[207] The court evidently placed great significance on the difference between ''purity,'' which was not defined by the regulation, and ''quality,'' which

[189] *See Grove Fresh I*, 720 F. Supp. at 716.
[190] *Id.* at 715.
[191] *Id.*; *see* 21 C.F.R. § 146.145.
[192] *See Grove Fresh I*, 720 F. Supp. at 716.
[193] *Id.*
[194] *Id.*
[195] *Grove Fresh Distribs., Inc. v. Everfresh Juice Co.*, Nos. 89 C 1113, 89 C 1117, 89 C 1118, , slip op. at *3 (N.D. Ill. Nov. 29, 1989) *(Grove Fresh II)*.
[196] *Id.*
[197] *Id.*
[198] *See POM Wonderful*, 679 F.3d at 1176-78.
[199] Order at 7-8, *Merck Eprova AG v. ProThera, Inc.*, No. 08 Civ. 35 (RMB)(JCF) (S.D.N.Y. Oct. 20, 2010), ECF No. 94. The defendant advertised its supplement as containing only ''L-5-MTHF,'' a ''pure'' form of folate, when in fact the supplement contained ''D,L-5-MTHF,'' a mixture of ''D-5-MTHF'' and L-5-MTHF. *Id.* at 3.
[200] *See id.* at 7.
[201] Mem. & Order at 2, *Sirius Labs., Inc. v. Rising Pharms., Inc.*, No. 03 C 6965 (N.D. Ill. Jan. 7, 2004), ECF No. 14. The USP establishes standards for certain drug ingredients, and some FDA regulations incorporate USP standards. *Id.* at 2. However, the USP is not a part of FDA or of the government. *Id.*
[202] *Id.* at 5.
[203] *See id.* at *5-6.
[204] Mem. & Order at 3, *Vt. Pure Holdings, Ltd. v Nestle Waters N. Am. Inc.*, No. Civ.A.03-11465-DPW, (D. Mass. Mar. 28, 2006), ECF No. 195.
[205] Beverages: Bottled Water, 60 Fed. Reg. 57076, 57124 (Nov. 13, 1995); *see* 21 C.F.R. § 165.110.
[206] Mem. & Order at 22, *Vt. Pure Holdings, Ltd. v Nestle Waters N. Am. Inc.*, No. Civ.A.03-11465-DPW, (D. Mass. Mar. 28, 2006), ECF No. 195.
[207] *Id.* at 24; *see* Beverages: Bottled Water, 60 Fed. Reg. 57,076, 57,099 (Nov. 13, 1995) (''The agency is not convinced that it should use its resources to define the term 'pure' at this time but will continue to discourage its use.'').

was defined.[208] Interestingly, the court then grouped purity and quality together in concluding that the plaintiff's Lanham Act claims challenging the ''*quality*, *purity*, treatment, contamination, and source'' of the defendant's bottled water were not precluded.[209] While the apparent internal inconsistency in the court's holding is confusing, the decision nevertheless illustrates how a Lanham Act claim can potentially avoid preclusion, even when the claim implicates issues governed by a specific, final FDA regulation.

F. *Drug Equivalency-Related Claims*

Drug manufacturers often make claims that their product is ''equivalent'' to or a ''generic'' of a competitor's product. Whether these claims can be challenged under the Lanham Act often depends on whether the comparison is being made with an FDA-approved drug or an unapproved drug. For drugs approved under new drug applications (NDAs) and abbreviated new drug applications (ANDAs), FDA publishes therapeutic equivalence evaluations in what is known as the Orange Book.[210] Healthcare professionals use the Orange Book to determine which generic drugs may be substituted for more expensive pioneer drugs.[211] Drugs marketed without an approved NDA or ANDA do not appear in the Orange Book.[212]

1. *Promotional claims of equivalence for an FDA-approved, Orange Book-listed drug are typically not actionable.*

Lanham Act claims asserting that an ANDA-approved, Orange Book-listed drug is falsely advertised as equivalent to the pioneer Orange Book-listed drug are generally unsuccessful.[213] For example, in *Wyeth v. Sun Pharmaceutical Industries, Ltd.*, FDA had approved defendant's ANDA for a generic version of the plaintiff's drug for the treatment of gastrointestinal disorders and had found defendant's generic was ''AB''-rated, meaning that studies established the bioavailability and bioequivalence of the defendant's drug.[214] The court rejected the plaintiff's challenge to the defendant's advertising of its drug as a ''generic equivalent.''[215] Because the FDA had already determined that the defendant's drug was equivalent to the plaintiff's drug, the court refused to permit the plaintiff to use the Lanham Act to undermine the validity of FDA's determination.[216]

A twist on this fact pattern arose in *GlaxoSmithKline v. Teva Pharmaceuticals* where the FDA originally approved the defendant's ANDA and rated the defendant's generic drug as bioequivalent but later reversed course based on new information.[217] The defendant argued that Lanham Act liability could not be imposed for the time period in which FDA's original bioequivalence decision was in effect.[218] The court disagreed, stating: ''FDA findings have a preclusive effect on Lanham Act liability . . . because courts should not second guess the scientific determinations of the FDA as the FDA is better suited and statutorily enabled to make such decisions.''[219] Because FDA had ultimately found that the branded and generic versions of the drug were not bioequivalent, the court held that a Lanham Act claim was not precluded.[220] Given that Lanham Act liability ''does not require intent, knowledge, recklessness, or negligence'' by the defendant, the court concluded that the defendant's ''[good] faith reliance'' on the FDA's original bioequivalence decision was not dispositive.[221]

2. *Promotional claims of equivalence between unapproved drugs that are not listed in the Orange Book are typically actionable.*

Lanham Act claims asserting that an unapproved drug is falsely advertised as a generic of, equivalent to, or substitutable with another unapproved drug are generally not precluded because the FDA does not affirmatively assess the equivalence of unapproved drugs, which are not listed in the Orange Book.[222] The overwhelming majority of courts have held that such equivalency-related advertising claims for unapproved drugs can be challenged under the Lanham Act.[223]

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[208] *See* 21 C.F.R. § 165.110(b).

[209] Mem. & Order at 25-26, *Vt. Pure Holdings, Ltd. v Nestle Waters N. Am. Inc.*, No. Civ.A.03-11465-DPW, (D. Mass. Mar. 28, 2006), ECF No. 195. (emphasis added).

[210] FDA, *Approved Drug Products With Therapeutic Equivalence Evaluations* iv (34th ed. 2013), http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm#Therapeutic%20Equivalence%20Evaluations%20Codes (''Orange Book''); *see also* 21 U.S.C. § 355(j)(7)(A).

[211] *See Wyeth v. Sun Pharm. Indus., Ltd.*, No. 09-11726, 2010 BL 45158, at *1-2 (E.D. Mich. Mar. 2, 2010).

[212] *See* Orange Book, *supra* note 210, at iv.

[213] *See Wyeth*, 2010 BL 45158, at *6-7.

[214] *Id.* at *2.

[215] *Id.* at *6.

[216] *Id.* at *7.

[217] *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, No. 13-726, slip op. at 2-4 (E.D. Pa. Mar. 10, 2014).

[218] *See id.* at 5, 9 (''Defendant claims that this later decision did 'nothing to change the fact that [the generic drug] was, until that change of position, rated AB3 and found bioequivalent,' and that the 'FDA's change of position cannot be the basis for retroactive liability.' '').

[219] *Id.* at 9-10.

[220] *Id.*

[221] *Id.* at 9.

[222] *See Wyeth v. Sun Pharm. Indus., Ltd.*, No. 09-11726, 2010 BL 45158, at *6-7 (E.D. Mich. Mar. 2, 2010).

[223] *See Mylan*, 7 F.3d at 1138; *Ferring Pharms., Inc. v River's Edge Pharms., LLC*, No. AW-09-02601, 2010 BL 181718, at *8 (D. Md. Aug. 6, 2010); *Graceway Pharms., LLC v. River's Edge Pharms., LLC*, No. 2:08-CV-0067-RWS, 2009 BL 241266, at *14 (N.D. Ga. Nov. 6, 2009); *Healthpoint, Ltd. v. Allen Pharm., LLC*, No. SA-07-CA-0526-XR, 2008 BL 55555, at *20 (W.D. Tex. Mar. 18, 2008); *Axcan Scandipharm Inc. v. Ethex Corp.*, 585 F. Supp. 2d 1067, 1075-76, 2007 BL 129529 (D. Minn. 2007); *Pediamed Pharms., Inc. v. Breckenridge Pharm., Inc.*, 419 F. Supp. 2d 715, 724-26 (D. Md. 2006); *Schwarz Pharma, Inc. v. Breckenridge Pharm., Inc.*, 388 F. Supp. 2d 967, 975 (E.D. Wis. 2005); *Healthpoint, Ltd. v. Ethex Corp.*, No. SA-01-CA-646-OG, 2004 BL 2865, at *27 (W.D. Tex. July 14, 2004); *Solvay Pharms., Inc. v. Global Pharms.*, 298 F. Supp. 2d 880, 884-85, 69 U.S.P.Q.2d 1530 (D. Minn. 2004); *Solvay Pharms., Inc. v. Ethex Corp.*, No. Civ. 03-2836 (JRT/FLN), 2004 BL 4082, at *5 (D. Minn. Mar. 30, 2004); *Healthpoint, Ltd. v. Stratus Pharms. Inc.*, 273 F. Supp. 2d 769, 792-93 (W.D. Tex. 2001); *Healthpoint, Ltd. v. Ethex Corp.*, 273 F. Supp. 2d 817, 845 (W.D. Tex. 2001). *But see Stiefel Labs., Inc. v. Brookstone Pharm., LLC*, 535 Fed. App'x 774, 777-78, 2013 BL 218975 (11th Cir. Aug. 19, 2013) (per curiam) (holding that plaintiff failed to present sufficient evidence to establish that defendant's advertising statements claiming generic equivalency were literally false); *Ethex Corp. v. First Horizon Pharm. Corp.*, 228 F. Supp. 2d 1048, 1055 (E.D. Mo. 2002) (dismissing Lanham Act claims based on marketing of unapproved drug as

   ISSN 0148-7965

Where the FDA has not indicated any intent to determine whether two unapproved drugs are equivalent, resolution of a plaintiff's Lanham Act claims is unlikely to ''usurp the role of the FDA.''[224]

This line of cases is distinguishable from cases discussed above in Part III.A.2, such as *Eli Lilly & Co. v. Roussel Corp.* and *Barr Laboratories, Inc. v. Quantum Pharmic, Inc.*, which also involved equivalency-related claims in advertising. While a false advertising claim based on a competitor's use of equivalency-related claims to imply FDA approval is generally not permitted,[225] a false advertising claim that *directly* challenges the equivalency-related claim is permitted.[226] So long as the plaintiff alleges, ''the defendant's advertising is false because its unapproved drug is not actually equivalent to my unapproved drug,'' the Lanham Act claim may proceed. Of course, to ultimately succeed in a lawsuit, the plaintiff has the burden to establish that the defendant's drug is not actually equivalent.[227]

IV. Conclusion

The Lanham Act offers firms the ability to remedy competitive harm privately without government intervention. The power of the Lanham Act's false advertising provisions, however, may be limited in the context of claims involving FDA-regulated products because of the related defenses of preclusion and primary jurisdiction. Through dozens of court decisions involving the full range of FDA-regulated products, the legal standards applicable to preclusion and primary jurisdiction in Lanham Act cases have gradually emerged. The framework and principles described in this article are intended as a first step toward greater consistency in the litigation and adjudication of cases positioned at the intersection of the Lanham Act and the FFDCA.

To develop effective regulatory and affirmative litigation strategies, FDA-regulated companies need to know when they can address false advertising by initiating a Lanham Act challenge, and whether it would be prudent to petition FDA to initiate enforcement. Moreover, to realistically assess litigation risk, FDA-regulated companies need to know whether particular labeling and advertising claims could be successfully challenged by competitors under the Lanham Act. Legal counsel with expertise in both Lanham Act and FDA regulatory matters are essential to assist FDA-regulated companies in navigating these complex issues.

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generic or alternative to competitor's unapproved drug because ''the word 'generic' implies FDA endorsement and certain FDA-defined concepts'').

[224] *E.g.*, *Allen Pharm.*, 2008 BL 55555, at *15-16; *Schwarz Pharma*, 388 F. Supp. 2d at 975.

[225] *See Eli Lilly & Co. v. Roussel Corp.*, 23 F. Supp. 2d 460, 477 (D.N.J. 1998); *Barr Labs., Inc. v. Quantum Pharmics, Inc.*, No. 90-CV-4406, slip op. at *11 (E.D.N.Y. Feb. 7, 1994).

[226] *E.g.*, *Pediamed Pharms.*, 419 F. Supp. 2d at 725-26; *Solvay Pharms.*, 298 F. Supp. 2d at 885.

[227] *See Stiefel Labs.*, 535 Fed. App'x at 777-78.