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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

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| JHP PHARMACEUTICALS, LLC,a Delaware limited liability company,<br><br>Plaintiff,<br><br>v.<br><br>HOSPIRA, INC., a Delaware corporation; INTERNATIONAL MEDICATION SYSTEMS, LTD., a Delaware corporation; and AMERICAN REGENT, INC., a New York corporation,<br><br>Defendants. | Case No. CV 13-07460 DDP (JEMx)<br><br>**ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTIONS TO DISMISS**<br><br>[Dkts 60 & 61] |

Presently before the court are two motions to dismiss the complaint brought by Par Sterile Products, LLC, against the Defendants American Regent, Inc., Hospira, Inc., and International Medical Systems, Ltd. The complaint alleges false or misleading advertising and labeling, based on the Lanham Act and equivalent state statutes. The Defendants' motions essentially argue that this Court, in deciding the case, would intrude on matters Congress has left exclusively to the discretion of the FDA. The Plaintiff,

on the other hand, argues that its complaint does not rest on matters requiring the expertise and authority of the FDA to resolve, and dismissal is not appropriate.

For reasons discussed below, the Court grants the motions in part and denies them in part.

## I. BACKGROUND

### *A. Factual Background*[1]

Par Sterile Products, LLC ("Par") is a manufacturer of injectable epinephrine under the brand name ADRENALIN. Defendants American Regent, Inc. ("American Regent"), Hospira, Inc. ("Hospira"), and International Medical Systems, Ltd. ("IMS") (collectively, "Defendants") are manufacturers of other injectable epinephrine products.

In 2012, Par (then known as JHP Pharmaceuticals, LLC) submitted a New Drug Application ("NDA") for its 1 mL and 30 mL injectable epinephrine products to the U.S. Food and Drug Administration ("FDA") under the brand name ADRENALIN. (Compl. ¶¶ 3-4.) On December 7, 2012, the FDA, pursuant to its power under the Food, Drug, and Cosmetic Act ("FDCA"), granted JHP approval to market and sell the 1 mL version of ADRENALIN. (Id. ¶¶ 5-6.)[2] Par

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[1]Both Par and Defendants Hospira and IMS have submitted to the Court additional material in support of their positions. "Generally, a district court may not consider any material beyond the pleadings in ruling on a Rule 12(b)(6) motion." Hal Roach Studios, Inc. v. Richard Feiner & Co., Inc., 896 F.2d 1542, 1555 n.19 (9th Cir. 1989). Therefore, the Court declines to consider, in ruling on these motions, either the Declaration of Harold Storey, submitted by Par, or the Declaration of Jeffrey LeVee, submitted by Hospira and IMS. This section draws exclusively from the complaint for the facts alleged.

[2]The NDA for the 30 mL ADRENALIN product was still pending at the time JHP filed its complaint. (Compl. ¶ 4.)

alleges that it invested millions of dollars in complying with the FDA approval process. (Id. ¶¶ 50-51.)

Par alleges that the Defendants all sell injectable epinephrine products which are not FDA-approved (Compl. ¶¶ 55, 57), an allegation which no Defendant denies. Par also alleges that the Defendants mislead the public in four different ways.

First, Par alleges that the Defendants represent to consumers, either overtly or through misdirection, that their products are FDA-approved, when they are not. (Compl. ¶ 71.)

Second, Par alleges that the Defendants misleadingly advertise their products as "safe" and "effective."[3]

Third, Par alleges that the Defendants advertise products that are "illegal" to sell or market under the FDCA (Id. ¶¶ 56-57), while representing to wholesalers and the public that they abide by the law. Par thus alleges that the Defendants are misleading wholesalers and the public as to the legality of their products.

Fourth, Par alleges that the Defendants omit from their product labeling certain injection location and adverse reaction information that Par's product *must* carry as part of its FDA-approved labeling. This, Par contends, misleads the public into thinking that Par's product is *more* dangerous than the generics, because it can only be administered in certain locations and can cause certain adverse reactions.

[3]Throughout the complaint, Par's constant refrain is that the Defendants market their products as "safe, effective, and FDA-approved." (Compl. ¶ 71.) However, for reasons that will be explained below, the Court finds it appropriate to separate the safety/effectiveness issues from the question of FDA approval.

Par asserts a claim against the Defendants for each of these representations under the Lanham Act, 15 U.S.C. § 1125(a)(1), which forbids false or misleading advertising.[4] Par also alleges actual injury, in the form of both competitive disadvantage and harm to reputation and goodwill.

Defendants counter that Par's Lanham Act claims should be dismissed, either because they are precluded altogether by the FDCA, because Par has failed to exhaust its administrative remedies, or because the FDA has primary jurisdiction over the claims and the case should be referred to the agency for a ruling. (Def. American Regent's Mot. Dismiss, § II; Defs. Hospira and IMS's Reply, § I; Def. American Regent's Reply, "Argument.") Defendants Hospira and IMS also raise the issue of the factual sufficiency of Par's claims. (Defs. Hospira and IMS's Mot. Dismiss, § I.C.2.)

*B. Procedural Background*

The initial complaint in this matter was filed on October 8, 2013, and the Defendants filed motions to dismiss on November 27, 2013. On February 3, 2014, Judge Michael Fitzgerald held a hearing on the motions. Ultimately, however, the Court ordered the motions denied without prejudice and the case stayed, pending the resolution of another Lanham Act/FDCA case in the Supreme Court, POM Wonderful LLC v. Coca-Cola Co., 134 S.Ct. 2228 (2014).

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[4]Par also alleges violations of the California Business and Professions Code, §§ 17200 and 17500, which similarly prohibit misleading advertising. These state law claims, however, are not substantively addressed in the motions currently under consideration, however, as all Defendants agree that the state claims are "substantially congruent" to the Lanham Act claims. (Def. American Regent's Mot. Dismiss, § III.A.; Defs. Hospira and IMS's Mot. Dismiss, § II.) Par similarly focuses its arguments in opposition on the Lanham Act claims.

POM Wonderful was decided June 12, 2014. On June 19, 2014, the Plaintiff in this case filed notice of the decision, and on July 23, 2014, the Defendants filed new motions to dismiss, which are the subject of this order.

**II. LEGAL STANDARD**

A complaint may be dismissed under Rule 12(b)(6) only if it "either (1) lacks a cognizable legal theory or (2) fails to allege sufficient facts to support a cognizable legal theory." Somers v. Apple, Inc., 729 F.3d 953, 959 (9th Cir. 2013). "All allegations of material fact in the complaint are taken as true and construed in the light most favorable to the plaintiff." Williams v. Gerber Products Co., 552 F.3d 934, 937 (9th Cir. 2008). "When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." Ashcroft v. Iqbal, 556 U.S. 662, 679 (2009).

**III. DISCUSSION**

*A. Failure to Exhaust Administrative Remedies*

American Regent, alone among the Defendants, raises the issue of failure to exhaust administrative remedies. It notes that under 21 C.F.R. § 10.45(b), citizens are required to submit a Citizen's Petition to the FDA "before any legal action is filed in a court complaining of the [agency's] action or failure to act." Were Par's claim that the FDA had acted unlawfully, or that the FDA had failed to act where it was required to do so, exhaustion would come into play. Par makes no such claim, nor indeed any claim against the FDA. Exhaustion of administrative remedies is not required, or even possible, here.

*B. The Lanham Act, the FDCA, and the Scope of the* POM Wonderful *Holding*

Because this action was stayed pending the outcome of the POM Wonderful case in the Supreme Court, this Court begins its analysis with the question of how, if at all, that decision has changed the law of preclusion with regard to Lanham Act cases and the FDCA.

The Lanham Act broadly regulates representations made in the course of commerce. It creates a cause of action against any person who "uses in commerce any . . . false or misleading description of fact, or false or misleading representation of fact, which . . . misrepresents the nature, characteristics [or] qualities . . . of his or her or another person's goods, services, or commercial activities." 15 U.S.C. § 1125(a)(1). The purpose of the Act is "to protect persons engaged in such commerce against unfair competition" and "to prevent fraud and deception." 15 U.S.C. § 1127.

The Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-399f, on the other hand, is intended "primarily to protect the health and safety of the public at large." POM Wonderful, 134 S. Ct. at 2234. Although the FDCA, too, regulates the labeling and advertising of drugs, see 21 U.S.C. § 352, enforcement is not through a private cause of action, but almost exclusively through the actions of the FDA. Apart from a few situations in which states may initiate enforcement actions, "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337.

The Lanham Act and the FDCA are thus two discrete statutory schemes that can regulate the advertising, marketing, and labeling

of food and drugs. Neither, however, precludes the other. In POM Wonderful, the Supreme Court held that "the FDCA and the Lanham Act complement each other" and that "Congress did not intend the FDCA to preclude Lanham Act suits . . . ." 134 S. Ct. at 2241. The Court noted that while "[e]nforcement of the FDCA and the detailed prescriptions of its implementing regulations is largely committed to the FDA," that agency "does not have the same perspective or expertise in assessing market dynamics that day-to-day competitors possess." Id. at 2238. Thus, the two statutes serve different functions and draw on different areas of expertise.

On the other hand, while articulating a broad vision of the statutes as compatible and complementary, the Court did, in passing, preserve the possibility that *some* Lanham Act suits might be precluded by the FDCA:

> *Unlike* other types of labels regulated by the FDA, *such as drug labels*, it would appear the FDA *does not preapprove* food and beverage labels under its regulations and instead relies on enforcement actions, warning letters, and other measures.

Id. at 2239 (citation omitted) (emphases added).

This passage suggests that, at a minimum, the Court might find a Lanham Act claim precluded by the FDCA where it turns on the content of a drug label, especially if that drug label were pre-approved by the FDA.

The Court further suggested, referencing Geier v. American Honda Motor Co., 529 U.S. 861 (2000), that a Lanham action might be barred where "the agency enacted a regulation deliberately allowing manufacturers to choose between different options," or where the Plaintiff's grounds for the Lanham Act claim otherwise conflict

with an affirmative policy judgment by the FDA. POM Wonderful, 134 S. Ct. at 2241.

There also exists a considerable body of circuit law, pre-POM Wonderful, counseling restraint by courts in approaching Lanham suits with regard to food and drug labeling and advertising. For example, the Ninth Circuit held, in PhotoMedex, Inc. v. Irwin, 601 F.3d 919 (9th Cir. 2010), that "a private action brought under the Lanham Act may not be pursued when, as here, the claim would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation."

PhotoMedex was the primary case relied on by the lower courts in POM Wonderful, and although it was not specifically overruled, its precedential value may be limited. But even PhotoMedex recognized that the FDCA did not fully bar Lanham Act claims, where the law was clear and did not require the FDA's expertise or rulemaking authority to determine:

> If, for example, it was clear that an affirmative statement of approval by the FDA was required before a given product could be marketed and that no such FDA approval had been granted, *a Lanham Act claim could be pursued for injuries suffered by a competitor as a result of a false assertion that approval had been granted*.

PhotoMedex, 601 F.3d at 924-25 (emphasis added). And other circuits have similarly concluded that where the issue of FDA approval is straightforward, a Lanham action is viable. See Alpharma, Inc. v. Pennfield Oil Co., 411 F.3d 934, 939 (8th Cir. 2005) (surveying the precedent of multiple circuits and concluding

that Lanham Act claims "concerning representations of FDA approval" are viable *unless* they would require a "preemptive determination" of an issue within the FDA's exclusive authority).

Thus, although the extent of the shift in doctrine after POM Wonderful is not entirely clear, both the Supreme Court in that case and the Circuits in prior case law make clear two things. First, Lanham Act claims (even with regard to FDA approval) are not, as a general matter, precluded or barred by the FDCA. But second, *some* claims *may* require the expertise of the FDA to resolve.

Given the strong holding in favor of Lanham claims in POM Wonderful, all Defendants understandably seek to limit the reach of that decision, arguing that the case and its holding were about food labels *only* and did not reach the labeling, marketing, or advertising of drugs. The broad language of the opinion, however, does not support that view.

It is true that the Court makes frequent mention of "food and drink" or "food and beverage" in the course of its opinion, e.g., POM Wonderful, 134 S. Ct. at 2334 ("The FDCA prohibits the misbranding of food and drink."); id. at 2237 ("[F]ood and beverage labels regulated by the FDCA are not, under the terms of either statute, off limits to Lanham Act claims."); id. at 2238 ("Although both statutes touch on food and beverage labeling . . . ."); etc. And, as noted above, the Court suggests a difference between food labeling, which is not subject to FDA pre-approval, and drug labeling, which is. Id. at 2239.

But the arguments, logic, and holding of *POM Wonderful* are couched in much broader language and strongly suggest a more wide-

ranging application. For example, the Court's argument that the Lanham Act draws on the market expertise of competitors, id. at 2238, does not depend on anything peculiar to food and beverage labeling. Nor does its argument that "neither the Lanham Act nor the FDCA, in express terms, forbids or limits Lanham Act claims challenging labels that are regulated by the FDCA," id. at 2237; nor does its point that "the Lanham Act and the FDCA have coexisted since the passage of the Lanham Act in 1946" and Congress has never sought to address preclusion by one or the other. Id.

The logical building blocks of the Court's specific holding with regard to food and beverage labeling would seem to be equally applicable to food and beverage advertising, drug marketing, medical device labeling, cosmetics branding, or any other kind of marking or representation which would fall under both the Lanham Act and the FDCA, *unless* preclusion is required for some specific reason.[5] The general presumption following POM Wonderful, then, is that Lanham Act claims with regard to FDCA-regulated products are permissible and, indeed, desirable. Id. at 2231 ("Allowing Lanham Act suits takes advantage of synergies among multiple methods of regulation.").

*C. Par's Lanham Act Claims*

Having established POM Wonderful's general presumption in favor of Lanham Act claims and against preclusion, the Court now turns to each of Par's bases for its claims.

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[5]As noted above, the Supreme Court suggested two such reasons in POM Wonderful: the FDA may have pre-approved a particular labeling scheme, as in the labeling of FDA-approved drugs; or the agency may have authorized a menu of possible lawful choices for manufacturers, as was the case in Geier. (The common element, of course, is positive regulatory action in the matter by the FDA.)

1. FDA Approval

Par's fundamental argument with regard to FDA approval is that it is a sort of "Good Housekeeping Seal" for pharmaceuticals: it is the government's imprimatur on a product, indicating quality, safety, and desirability. Although some drugs may be lawfully sold without FDA approval, Part III.C.3 *infra*, if a product *has* been approved, consumers may take some assurance that it has been properly tested and meets the agency's minimum quality standards. This makes an FDA-approved product a more attractive product, whether at the wholesale, retail, or end user level. But it can also be expensive to get approval for a drug, so a company that chooses to invest in getting approval may operate at a competitive disadvantage if other companies can falsely represent to the public that their unapproved products are FDA-approved. Thus, representations that a drug is approved when it is not undermine the Lanham Act's public policy goals both by confusing consumers and by enabling unfair competition by producers who have not bothered to get FDA approval.

Par alleges that Defendants have misrepresented their products as being FDA-approved in several ways. First, Par alleges that Hospira advertises its product "as an NDA product . . . when, in fact, Hospira has not obtained FDA approval of such an NDA." (Compl. ¶ 70.) Second, Par alleges that Hospira, at least, advertises that Par's ADRENALIN is the "brand name equivalent" of its own product, and that it is a "generic" version of Par's product.[6] In a more general way Par alleges that Defendants

[6]Par introduced these specific allegations against Hospira (continued...)

encourage purchasers to think of their products as "comparable to or interchangeable with" Par's product. (Id. at ¶ 101.) Par contends that consumers will believe that Defendants' unapproved products are interchangeable with Par's approved one. Finally, Par alleges that Defendants advertise via certain industry lists, and that consumers expect the products on such lists to be "branded drugs or generic products," although Defendants' products are not "generics" as defined by the FDA. (Id. at ¶ 70.)

Defendants argue that claims based on such factual allegations are precluded, even post-POM Wonderful. Defendant American Regent cites to a recent case in the District of Utah, where the court found precluded a company's Lanham claim that a competitor was "falsely advertising that the current [medical device] model has FDA approval." Catheter Connections, Inc. v. Ivera Med. Corp., No. 2:14-CV-70-TC, 2014 WL 3536573, *1, *6 (D. Utah July 17, 2014). But that case dealt with *re*-approval of new models of *existing* medical devices, a circumstance under which the FDA leaves it to the manufacturer, in the first instance, to determine whether it must apply for approval again or assume that the approval carries over. Id. at *5. Thus, the manufacturer there could plausibly claim that its product was, in fact, approved, at least until the FDA determined otherwise–a determination that would, of course, be entirely within the agency's purview. That is obviously very

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[6](...continued)
only at oral argument. Ordinarily, the Court would be reluctant to consider such late allegations as part of the complaint. However, because they sharpened the debate during oral argument, were adequately argued by Defendants, and were consistent with the other, more general allegations in the Complaint, the Court includes them in this discussion.

different from the present case, where the Defendants have never had (and do not claim to have had) their products approved in the first place.

In short, Par's claim is not precluded.

Defendants also argue that Par's claim falls under the "primary jurisdiction" of the FDA. Under the primary jurisdiction doctrine, a court, though having jurisdiction to hear the complaint, may in some situations be required to "refer" the matter to an administrative agency for resolution of a particular technical issue. See Reiter v. Cooper, 507 U.S. 258, 268 (1993) ("[C]laims properly cognizable in court [may] contain some issue within the special competence of an administrative agency."). The doctrine applies where there is "(1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory scheme that (4) requires expertise or uniformity in administration." United States v. Gen. Dynamics Corp., 828 F.2d 1356, 1362 (9th Cir. 1987).

There is no need to invoke primary jurisdiction doctrine as to this claim. In this instance, it takes no special expertise to determine whether the FDA has granted approval or not; nor are there "uniformity of administration" concerns in the court making that simple factual determination. The FDA itself maintains a comprehensive list of approved drugs, see FDA, "Drugs@FDA," FDA.gov, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm (last visited Aug. 28, 2014), and while there may be cases where

approval is a gray area, no Defendant has argued that this is one. Indeed, the fact that the Defendants' drugs are unapproved is not contested by any party.

The same thing is true of the term "generic." To be declared a "generic" drug by the FDA, a product must go through an approval process prescribed by the agency. See "Generic Drugs: Questions and Answers," FDA.gov (Sept. 3, 2013), http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm. But the FDA maintains lists of approved generics, just as it does for brand-name products. Id. If all that Par alleges is that Defendants are advertising their products as approved generics when they are not in fact approved, the Court need not refer the question to the FDA's expertise to make factual determinations.

Primary jurisdiction is not a bar to Plaintiff's claims here.

Defendants also allege that Par's complaint is factually insufficient to support its Lanham claim. Defendants argue that Par has not alleged specific statements by the Defendants representing that their products are FDA-approved. Defendants then cite primarily to Mylan Labs., Inc. v. Matkari, 7 F.3d 1130 (4th Cir. 1993) for the proposition that a plaintiff cannot show that the defendant implied FDA approval solely by introducing evidence that the defendant put the product on the market.

With regard to Defendant Hospira, Par has, in fact, alleged a specific representation: Par alleges that Hospira advertises its product as "an NDA product." (Compl. ¶ 70.) While that is not precisely the same as saying that the product is "FDA-approved," it could easily be construed that way by the public, who should not

bear the burden of uncovering information that contradicts the impression given by misleading advertising. See, e.g., Williams v. Gerber Products Co., 552 F.3d 934, 939-40 (9th Cir. 2008) (holding that the misleading labeling of a largely juice-free candy as "fruit juice snacks" was not saved from a false advertising claim by an FDA-approved ingredient list on the side of the box). Therefore Par has made a plausible allegation that Hospira has made misleading statements about its products' FDA approval status.

With regard to the other two defendants, however, it is not so clear. Mylan, though not binding on this Court, makes a compelling point: merely putting the product on the market is probably not a representation that the product is FDA-approved. At the other end of the factual spectrum, the Ninth Circuit has said that an actual "false assertion" that the product was approved could sustain a Lanham Act claim where "it was clear that . . . no such FDA approval had been granted." PhotoMedex, 601 F.3d at 924-25.

Par's complaint falls somewhere between those two clear poles. With regard to American Regent and IMS, at least, Par alleges no overt "false assertion." On the other hand, Par's argument is more subtle than that of the plaintiff in Mylan. Par does not merely allege that putting the product on the market creates a misleading impression that the drug is FDA-approved. Rather, it alleges that the Defendants put their products on industry "Price Lists," and that "buyers believe that all prescribed drugs identified on the Price Lists are . . . FDA-approved." (Compl. ¶ 71.) And it alleges that by listing their drugs as "generics," they are implying that their products are "equivalents" of Par's FDA-

approved product, which might mislead consumers into thinking that Defendants' products are also FDA-approved. (Id. at 70.)

The problem, for Par, is that when the alleged representation is not an overt false statement, but merely misleading in context, the evidentiary showing required to sustain a Lanham claim is higher. In such a case, "proof that the advertising actually conveyed the implied message and thereby deceived a significant portion of the recipients becomes critical." William H. Morris Co. v. Grp. W, Inc., 66 F.3d 255, 258 (9th Cir. 1995). Thus, to succeed on its claims against American Regent and IMS, Par must allege facts tending to show that the message "our product is FDA-approved" was actually conveyed to consumers by American Regent and IMS.

Here, Par does allege that consumers suffer actual confusion: "[B]uyers believe that all prescribed drugs identified on the price lists are . . . FDA-approved." (Compl. ¶ 71.) While Par has not yet produced actual evidence of these consumer beliefs, at the motion to dismiss stage, the Court can accept allegations of such facts as sufficient.

Par's Lanham Act claims that its competitors are falsely representing their products as having been FDA-approved are neither precluded by the FDCA nor within the primary jurisdiction of the FDA. Plaintiff's factual pleadings are sufficient to survive a motion to dismiss. As to the question of whether Defendants advertise their products as FDA-approved, the motion to dismiss is denied.

2. "Safe" and "Effective"

In its complaint, Par frequently alleges that the Defendants misleadingly represent their products as "safe, effective, and FDA-approved." (E.g., Compl. ¶ 72.) A determination of whether the Defendants' products are "safe" or "effective" might well fall within the primary jurisdiction of the FDA, or even be precluded entirely. However, the Court need not decide these issues today. Par alleges *no* facts to show that Defendants' products are either unsafe or ineffective. The repeated inclusion of such language may well be mere rhetorical excess on Par's part. However, to the extent that any of the Plaintiff's arguments about FDA approval rest on a determination of either safety or effectiveness, such arguments suffer a fatal lack of factual sufficiency. Thus, the sole question with respect to the surviving claim against Defendants is whether it overtly represents its products as being "FDA-approved," and *not* any question of safety or effectiveness.

3. Legality of the Defendants' Products

Par further alleges that the Defendants are falsely representing to consumers that their products "comply with all applicable laws, including the FDCA."[7] (Compl. ¶¶ 60, 87.) And at least respecting Defendants Hospira and IMS, the complaint alleges sufficient facts to support a finding of overt statements to this effect. For example, Hospira is alleged to claim on its website

[7]In its Opposition, Par seems to suggest that no finding of illegality is needed: "Par's complaint is not based on a violation of the FDCA; it is based on Defendants' deceptive advertising of their products as equivalent to Par's." (Opp'n § I.B.) However, because the complaint raises allegations that the Defendants are misleading consumers by claiming to comply with the law, the Court, to resolve that claim, would have to make a factual finding with regard to the alleged FDCA violations.

that its complies with "applicable laws and other requirements." (Compl. ¶ 62.)

However, unlike a mere determination that a drug is or is not FDA-approved, the allegation that the drugs are being sold *unlawfully* is an issue that would require a more complex finding from the agency. Of course, if there were a clear and absolute rule making it patently unlawful to market *any* drug without going through the FDA approval process, it might not be necessary for the FDA to make a specific finding regarding the Defendants' products for the court to be able to determine that Defendants' products do not comply with the FDCA. PhotoMedex, 601 F.3d at 924-25.

And at first blush, 21 U.S.C. § 355(a) would seem to provide such a clear rule: "No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug." As even Par admits (Opp'n, "Factual Background"), however, there are some exceptions to this seemingly clear rule. Specifically, not all drugs marketed are "new," and many older drugs, even when updated, are exempt from the strictures of § 355(a). See 21 U.S.C. § 321(p) (setting out grandfathered exceptions to the definition of "new drug"); see also FDA, Compliance Policy Guide Sec. 440.100 Marketed New Drugs Without Approved NDAs and ANDAs, FDA.gov (Sep. 16 2011), available at http://http://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074382.htm (discussing grandfather clauses in the FDCA and a "Prescription Drug Wrap-Up" program that brought many, but not all, old drugs into the fold of FDA approval).

In short, unlike the binary factual determination of whether Defendants' products are, in fact, FDA-approved, the question of legality directly implicates the FDA's rulemaking authority. The determination of whether a drug is "new," and whether it can be lawfully marketed under the FDCA, involves complex issues of history, public safety, and administrative priorities that Congress has delegated exclusively to the FDA.

That does not mean, however, that an allegation of illegality under the FDCA could *never* form the basis of a successful Lanham Act claim. As PhotoMedex and POM Wonderful both make abundantly clear, where the court is not called upon to make determinations within the exclusive purview of FDA authority, a Lanham Act claim may be heard, even if the subject of the claim touches the area of authority of the FDCA. Thus, this claim is not precluded as a categorical matter. If the Plaintiff were to pursue the matter with the FDA through its administrative procedures and obtain a clear statement from the agency that the Defendants are selling their products illegally or otherwise breaking the law, *and* if the Defendants at that point chose to affirmatively declare in their advertising that their products comply with the law, a federal court could hear a Lanham Act claim for false advertising.

But this Court cannot proceed on this claim without a clear statement by the FDA. To do so would be to arrogate the authority of the FDA to decide, at least in the first instance, the legality or illegality of marketing a particular substance. "It is clear to us that FDA has power to determine whether particular drugs require an approved NDA in order to be sold to the public. FDA is indeed the administrative agency selected by Congress to administer the

Act, and [it] cannot administer the Act intelligently and rationally unless it has authority to determine what drugs are 'new drugs' . . . and whether they are [grandfathered]." Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 624 (1973).

In short, in order to resolve Par's Lanham Act claim based a factual allegation that the Defendants are falsely claiming to comply with the law while in fact selling illegal products, the Court must resolve an issue that Congress has placed "within the jurisdiction of an administrative body having regulatory authority," under a comprehensive regulatory scheme. Gen. Dynamics Corp., 828 F.2d at 1362. And, crucially, this is not a question that can be resolved without expertise. Id. Moreover, Congress's decision to centralize authority to determine the legality of drug sales in the FDA was obviously intended to provide "uniformity of administration." Id. Thus, it seems clear that Par's Lanham Act claim with regard to legality requires a determination that is within the primary jurisdiction of the FDA.

4. Misleading Labeling

Finally, Par argues that the Defendants mislead the public by not including, in their packaging and labeling, all of the caveats and warnings that Par's product must carry under the terms of its FDA approval. This, it is alleged, creates the impression that Par's product is *less* safe, because it comes with *more* warnings than the Defendants' unapproved products.

Even if this allegation is true, Par faces several hurdles to basing a Lanham Act claim on it. First, because the deceit alleged is by implication rather than an overt false statement (such as "Par's ADRENALIN is less safe than our product!"), Par has the

burden of pleading at least some facts tending to show that the alleged implied message is actually transmitted to the consumer. William H. Morris, 66 F.3d at 258. Here the pleading is thin at best. Par does not allege facts tending to show that the negative message about its product is actually conveyed to consumers. Indeed, the message is at least ambiguous: a savvy consumer of pharmaceuticals, used to many pages of dire warnings, might well be put *on guard* by the lack of similar warnings on the Defendants' products.

Even if Par's pleading were sufficient to show that the alleged implied message is actually transmitted to consumers, however, the area of drug labeling was specifically singled out by the POM Wonderful Court as being one where the FDA takes a particularly active role. POM Wonderful suggested, at least obliquely, that drug labeling might be an area where Lanham Act claims *are* precluded.

Par argues that because the Defendants' products are unapproved, they are effectively unregulated by the FDA. (Opp'n § I.C.) There is, perhaps, some merit to this argument. Unlike the situation envisioned in POM Wonderful, where the FDA would have *pre-approved* a drug label, here Par correctly points out that the FDA has taken no action at all with regard to these labels. Thus, this case might not fall within POM Wonderful's caveat-in-dictum.

However, the Court need not resolve this thorny issue, because there is a third, truly fatal problem with Par's allegation: namely, it requires the Court to determine, as a matter of fact, that Par's ADRENALIN is *not* less safe than the Defendants' various products. After all, if ADRENALIN *were* less safe, the implied

message would not be false or misleading; it would be correct. Par may find it obvious that its product is not less safe than the Defendants' products, but it has not alleged any particular facts tending to prove the comparative safety of the various products involved.[8]

Because the Plaintiff's Lanham Act claim based on false or misleading labeling requires a showing of facts not properly pleaded, this claim is dismissed as to all Defendants.

**IV. CONCLUSION**

For all the reasons discussed above, Plaintiff's Lanham Act claim and corresponding state law claims based on false representations of FDA approval survive, and the Defendants' motions are denied.

Plaintiff's claims based on false or misleading representations that the Defendants's products comply with the law are dismissed without prejudice, so that the Plaintiff can, if it wishes, file a petition with the FDA to have its competitors' products declared unlawful.

Finally, any claims based on representations that the Defendants' products are "safe" and/or "effective" are dismissed. Claims that the Defendants' labels and packaging are misleading

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[8]Even if Par had alleged such facts, however, the safety determination would almost certainly require the scientific expertise of the FDA, and so would likely fall within the agency's primary jurisdiction.

because they imply that their products are safer than Plaintiff's are also dismissed.

The motions to dismiss are thus granted in part and denied in part.

IT IS SO ORDERED.

Dated: October 7, 2014

DEAN D. PREGERSON
United States District Judge