No. 13-

IN THE

Supreme Court of the United States

ATHENA COSMETICS, INC.,

Petitioner,

v.

ALLERGAN, INC.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

In *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), this Court unanimously held that the Federal Food, Drug, and Cosmetic Act ("FDCA") impliedly preempted a state-law tort claim that was predicated on an alleged violation of Food and Drug Administration ("FDA") rules governing the approval of an FDA-regulated product. More generally, *Buckman* explained, a state-law claim is preempted *whenever* "the existence" of the federal regulatory scheme "is a critical element" of the plaintiff's claim, because the FDCA's text "leaves no doubt" that Congress wanted that scheme administered "exclusively by the Federal Government." *Id.* at 349 n.4, 352-53.

Here, respondent alleged that petitioner violated one state's unfair competition law by selling a product without FDA pre-approval. FDA itself had declined to find such approval necessary, despite a protracted lobbying campaign by respondent. The lower courts nevertheless entertained respondent's private suit; stepped into FDA's shoes; made the regulatory determination that FDA had refused to make; and enjoined the sale of petitioner's product in California, unless petitioner seeks and obtains the very approval that FDA itself found unnecessary.

The question presented is whether, under *Buckman*, the FDCA impliedly preempts a private state-law claim for unfair competition premised on a party's purported failure to obtain FDA approval, where FDA itself has not imposed any such requirement.

PARTIES TO THE PROCEEDING AND RULE 29.6 STATEMENT

In addition to the parties named in the caption, Murray A. Johnstone, M.D. and Duke University were nominal plaintiffs in the district court and nominal appellees in the Court of Appeals, and Pharma Tech International, Inc., Product Innovations, LLC, Northwest Cosmetic Laboratories, LLC, and R & G Business LLC were defendants in the district court.

Pursuant to this Court's Rule 29.6, undersigned counsel state that Athena Cosmetics, Inc. is a privately held company. It has no parent corporation, and no publicly held company owns 10% or more of its stock.

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PETITION FOR A WRIT OF CERTIORARI

Petitioner Athena Cosmetics, Inc. respectfully submits this petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-19a) is reported at 738 F.3d 1350. Two of the four relevant district-court orders are unofficially reported at 2012 U.S. Dist. LEXIS 189655 (Pet. App. 46a-52a) and 2013 U.S. Dist. LEXIS 181933 (Pet. App. 20a-45a).

JURISDICTION

The court of appeals filed its opinion and entered its judgment on December 30, 2013. Pet. App. 1a-19a. On March 6, 2014, Chief Justice Roberts granted an extension of time for filing a petition for a writ of certiorari until May 15, 2014. No. 13A906. This Court has jurisdiction under 28 U.S.C. 1254(1).

CONSTITUTIONAL PROVISIONS, STATUTES, AND REGULATIONS INVOLVED

All pertinent constitutional provisions, statutes, and regulations are reproduced in the Petition Appendix at 98a-114a.

STATEMENT

Respondent Allergan, Inc. ("Allergan") sells a prescription drug called Latisse that treats

hypotrichosis, a medical condition characterized by abnormally inadequate eyelash growth. Petitioner Athena Cosmetics, Inc. ("Athena") sells a cosmetic eyelash conditioner called RevitaLash. Allergan sued Athena under California's "unfair competition" statute, and ultimately obtained an injunction that bans the sale of RevitaLash in California (but not in other states).

Crucially, Allergan did not argue below—much less prove—that RevitaLash was defective or unsafe, *cf. Wyeth* v. *Levine*, 555 U.S. 555 (2009); that Athena promoted RevitaLash deceptively, *cf. POM Wonderful LLC* v. *Coca-Cola Co.*, No. 12-761 (argued Apr. 21, 2014); or that Athena had unfairly tarnished Allergan's goodwill or reputation, *cf. Lexmark Int'l, Inc.* v. *Static Control Components, Inc.*, 134 S. Ct. 1377 (2014). Rather, in Allergan's words, its "unfair competition" claim arose "*purely as a result* of [Athena's] failure to obtain an approved new drug application" from FDA before selling RevitaLash. C.A. App. 500.

The district court determined that RevitaLash is a "drug" whose sale requires pre-approval under the FDCA and parallel provisions of California law. That conclusion, however, was directly contrary to FDA's position on the regulatory classification of cosmetic eyelash conditioners. Indeed, FDA has repeatedly stated that, in its view, products like RevitaLash are *not* drugs. C.A. App. 2879. But more fundamentally, how RevitaLash should be classified, and how Athena should be sanctioned (if at all) for failure to obtain "drug" approval, *are decisions Congress entrusted to*

FDA alone. Thus, Allergan's "lack-of-FDA-approval" claim did not belong in court.

The text of the FDCA is "clear . . . that Congress intended" the statute's requirements to "be enforced exclusively by the Federal Government." *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001); *see* 21 U.S.C. 337(a) ("all . . . proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States"). As *Buckman* held, § 337(a) does more than just bar *direct* private actions under the FDCA itself—it also "impliedly pre-empt[s]" claims "under state tort law" that are *functionally equivalent* to direct FDCA enforcement, as such claims pose the same threat to the statutory scheme. *Id.* at 343, 348; *see generally Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941) (state law is impliedly preempted when it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress").

The Federal Circuit concluded that Allergan's state-law claim did not subvert Congress's intent because the California rule that Allergan sought to enforce—*i.e.*, that new drugs require FDA approval—"parallel[ed]" that of the FDCA. Pet. App. 9a. In so ruling, the Federal Circuit misconstrued this Court's holdings that "parallel" claims under state law are not *expressly* preempted to mean that such claims cannot be preempted *at all*—a position that *Buckman* plainly disavowed.

The Federal Circuit's decision creates a direct circuit split regarding the preemption of state-law

"lack-of-FDA-approval" claims. More generally, it reflects the lower courts' entrenched confusion over the scope of implied preemption under § 337(a)—an issue of paramount importance to all FDA-regulated industries. And, in permitting a private plaintiff to obtain a single-state ban on a product's sale, the decision below poses an unprecedented threat to the national uniformity of the FDCA regime, and invites a tidal wave of novel private-enforcement claims.

Already this Term, this Court has called for the Solicitor General's views on a petition concerning the implied preemption of a state-law tort claim under § 337(a). *See* Petition for Certiorari, *Medtronic, Inc.* v. *Stengel*, No. 12-1351, 134 S. Ct. 375 (Oct. 7, 2013). Even more starkly than *Stengel*—which involved an injured consumer seeking money damages for failure to warn of a product defect—this petition presents the question of how far a private plaintiff may go without colliding with § 337(a). This Court should grant certiorari (perhaps as an illustrative companion case to *Stengel*) and reverse.[1]

A. The Parties And Their Products

Respondent Allergan is a multi-billion-dollar pharmaceutical company that sells, *inter alia*, a prescription drug called Latisse. The active ingredient in

[1] At minimum, this petition should be held pending resolution of the petitions in *Stengel* and in *Bank of America, N.A.* v. *Rose*, No. 13-662, which also concerns private enforcement of public statutes via California's unfair-competition law.

Latisse is bimatoprost, a prostaglandin analog that has been shown to grow eyelashes. Latisse is marketed as a drug that "treats" a medical condition—"hypotrichosis [*i.e.*, insufficient growth] of the eyelashes"— by "promoting [eyelash] *growth*." C.A. App. 364-65 (emphasis added).

Petitioner Athena is a small private cosmetics company founded in 2006. Its flagship product is an eyelash conditioner sold under the "RevitaLash" brand.[2] Eyelash conditioners are products used to beautify and enhance the *appearance* of eyelashes, which makes them cosmetics and not "drugs." Accordingly, Athena did not seek FDA approval before introducing RevitaLash for sale.

RevitaLash contains a compound called 3D. Like the bimatoprost found in Latisse, 3D is a prostaglandin analog; however, as explained below, this fact—in FDA's view—does not render RevitaLash a "drug." *Post* at 7-10. Since at least 2007, Athena has consistently labeled and promoted RevitaLash as a cosmetic product that, like mascara, "improve[s] the *appearance* and enhance[s] the *beauty*" of eyelashes, much the way traditional shampoos and conditioners improve the appearance and enhance the beauty of a person's hair.

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[2] Athena has sold a range of products under the RevitaLash brand. This case only concerns the RevitaLash eyelash conditioner, and the term "RevitaLash" as used herein refers solely to that product.

B. Regulatory Background

1. The Federal Regime

a. Drugs And Cosmetics

The FDCA, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. 301 *et seq.*), comprehensively regulates the sale of, *inter alia*, drugs and cosmetics. In some respects, the FDCA treats drugs and cosmetics alike. Both are subject to prohibitions against adulteration and misbranding. *See* 21 U.S.C. 351-52, 361-62; *Estée Lauder, Inc.* v. *FDA*, 727 F. Supp. 1, 2 (D.D.C. 1989). Thus, FDA may take action against either a drug or a cosmetic that it finds to be unsafe or deceptively promoted. In one crucial respect, however, drugs and cosmetics are treated very differently: since the enactment of the FDCA in 1938, drugs, but not cosmetics, have been subject to a premarket approval requirement. *See* 21 U.S.C. 355; *Estée Lauder*, 727 F. Supp. at 2.

The FDCA's drug-approval regime was a sharp break from prior law, both state and federal. *See Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 623 (1973) ("Prior to 1938 there was no machinery for the premarketing approval of drugs sold in commerce."); *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312, 341-42 (2008) (Ginsburg, J., dissenting) (before FDCA's enactment, "no state regulations required premarket approval of . . . drugs"). Before 1938, scattered state statutes imposed *ex post* penalties for the sale of drugs that were unsafe or fraudu-

lently promoted,[3] and the common law provided *ex post* monetary relief to consumers who were physically injured by defective drugs. *See Levine*, 555 U.S. at 566. But the notion of liability for the sale of a *safe* and *truthfully advertised* article, based solely on lack of preclearance, was unknown.

The new drug application ("NDA") process is expensive and time-consuming, both for applicants and for FDA itself. NDAs "typically run to hundreds of thousands of pages," and the process "takes an average of 15 years and costs in the range of 500 million dollars." Food and Drug Administration Modernization Act of 1997, S. Rep. 105-43, 1997 WL 394244, at *6. "FDA must conduct a robust scientific analysis" of every NDA, requiring a "review team" of "medical doctors, chemists, statisticians, microbiologists, pharmacologists, and other experts." Br. of the United States as *Amicus Curiae* in *Mutual Pharm. Co.* v. *Bartlett*, 2013 U.S. S. Ct. Briefs LEXIS 450, at *44 (Jan. 22, 2013).

b. The "Intended Use" Test

Whether an article is a "drug" or a "cosmetic" is thus a question of great consequence. The statutory test for classification, however, is murkier than one might expect.

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[3] *See generally* Wallace F. Janssen, *Outline of the History of U.S. Drug Regulation and Labeling*, 36 Food Drug Cosm. L.J. 420 (1981); Wallace F. Janssen, *America's First Food and Drug Laws*, 30 Food Drug Cosm. L.J. 665 (1975).

The FDCA defines "drugs" and "cosmetics" not by their ingredients or physical effects, but by their so-called "intended use." *See Estée Lauder*, 727 F. Supp. at 2; Peter Barton Hutt, *Reconciling the Legal, Medical and Cosmetic Chemist Approach to the Definition of a Cosmetic*, 3 CFTA Cosm. J., No. 3 (1971) ("the intended use of the product, rather than its inherent properties, control[s] its classification"). Specifically, a cosmetic is "[an] article[] *intended* to be . . . introduced into, or otherwise applied to the human body" for "cleansing, beautifying, promoting attractiveness, or altering the appearance." 21 U.S.C. 321(i)(1) (emphasis added). A drug, in contrast, is an "article[] *intended* for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and/or an "article[] (other than food) *intended* to affect the structure or any function of the body." *Id.* § 321(g)(1)(B)-(C) (emphasis added).[4]

The FDCA itself does not define "intended use," but legislative history suggests that Congress viewed the manufacturer's promotional claims as determinative. *See* S. Rep. No. 361, 74th Cong., 1st Sess. 4 (1935) ("The manufacturer of the article, through his representations in connection with its sale, can de-

[4] "Intended use" governs many other classifications under the FDCA. *See* Respondents' Br. on the Merits in *Buckman*, 2000 U.S. S. Ct. Briefs LEXIS 540, at *17 (Oct. 23, 2000) ("'Intended use' is at the heart of the FDCA regulatory scheme. It determines whether a product is a drug or device, the character of the product, the regulatory requirements to which it is subject, and the extent of those requirements." (citations omitted)).

termine the use to which the article is to be put."). An FDA regulation, 21 C.F.R. 201.128, defines "intended use" as the manufacturer's so-called "objective intent," as "determined by [its] expressions" or "the circumstances surrounding the distribution of the article."

Historically, in determining "intended use," FDA "looked solely at the actual statements made by [the] manufacturer in the marketplace about its product." Gregory Gentry, *Criminalizing Knowledge: The Perverse Implications of the Intended Use Regulations for Off-Label Promotion Prosecutions*, 64 Food & Drug L.J. 441, 445 (2009). In recent years, FDA has occasionally invoked other factors. *Id.* at 449-58; *see, e.g.*, 60 Fed. Reg. 41453, 41464 (Aug. 11, 1995). However, FDA continues to perceive that "[a] product's intended use is usually primarily a function of the manner in which a company characterizes its product in the marketplace." 59 Fed. Reg. 59820, 59822 (Nov. 18, 1994); *see, e.g.*, *Sigma-Tau Pharms.* v. *Schwetz*, 288 F.3d 141, 146-47 (4th Cir. 2002) (affirming FDA's decision to "rely[] primarily upon the [article's] labeling" and to disregard other "surrounding circumstances").

Courts recognize that the determination of "intended use" "entail[s] the exercise of judgment grounded in policy concerns," and often requires FDA to "balance" competing policy objectives. *Sigma-Tau*, 288 F.3d at 146, 148. Determining "intended use" is therefore quintessentially within FDA's primary jurisdiction. *See* 61 Fed. Reg. 44396, 44519 (Aug. 28, 1996) ("[I]t is within FDA's primary jurisdiction and

expertise to determine [an article's] intended use."); *Biotics Research Corp.* v. *Heckler*, 710 F.2d 1375, 1377 (9th Cir. 1983). Indeed, to Athena's knowledge, until this case, the "intended use" of an FDA-regulated article has *never* been determined in a private proceeding without FDA's participation.

Moreover, an article's "intended use" is not graven in stone. Rather, if the manufacturer's promotional claims change, an article's "intended use" can also shift. *See* 21 C.F.R. 201.128 ("[t]he intended uses of an article may change"); *United States* v. *Articles of Drug . . . Neptone*, Food Drug Cosm. L. Rep. ¶ 38,240 (N.D. Cal. 1983) (classification of product as a drug based on manufacturer's recent promotion did not "establish[] for all time that [the product] is a drug").

c. FDA's Consideration Of Eyelash Conditioners

FDA is well aware of the "eyelash conditioner" product category, and of RevitaLash in particular. The record strongly indicates that FDA *does not* consider products such as RevitaLash that do not make "eyelash growth" claims to be "drugs."

Starting in early 2007, Allergan complained to FDA that Athena's original RevitaLash product was an unapproved "drug" because it contained the same "active ingredient" as Allergan's drug Latisse, and purportedly was being marketed for eyelash "growth." Athena provided FDA with detailed information regarding its products and advertising, and represented to the Agency that it would refrain

from making further "growth" claims. FDA thereafter abstained from taking any enforcement action.

One particular exchange is especially telling. In May 2007, Allergan complained to FDA about RevitaLash and another eyelash conditioner manufactured by a co-defendant in the district court. Allergan asserted that both products required FDA "drug" approval because they contained prostaglandin analogs, and asked FDA to find that the products' lack of such approval rendered them illegal. The Agency's response rejected Allergan's interpretation of the "intended use" regulation, and specifically stated that the presence of a particular ingredient does not cause an eyelash conditioner to be a "drug." Moreover, FDA pointed out, even if an eyelash conditioner *was once* a drug based on the manufacturer's claims of eyelash growth, that product is *no longer* a drug if the manufacturer discontinues such claims. C.A. App. 2879.

Thereafter, Allergan recruited a member of Congress to lobby FDA to take action against cosmetic eyelash conditioners. In a 2010 response letter, FDA explained to the Congresswoman that it was "currently exploring its options for addressing products in this category." FDA stressed that "[a]s violative products are identified, FDA interacts with the [manufacturers] to protect public health." C.A. App. 2837-38. In a follow-up letter in 2011, FDA disagreed with the blanket assertion that eyelash conditioners "are unapproved new drugs" and reiterated that the Agency was "assessing" on a "product by product basis" whether "any such eyelash products are drugs as

defined by the [FDCA]." C.A. App. 2834.

d. FDA's Sole Enforcement Authority

When FDA perceives a statutory violation, the FDCA provides it with a "variety of enforcement options to make a measured response." *Id.* at 349; *see, e.g.*, 21 U.S.C. 332(a) (injunctions); *id.* § 333(a) (criminal penalties); *id.* § 333(b), (f) (civil fines); § 334(a) (seizures and forfeitures); § 334(g) (detention); § 336 (warning letters). Often, FDA will negotiate a settlement requiring corrective actions (*e.g.*, label changes) without a finding of liability. Br. of the United States as *Amicus Curiae* in *Warner-Lambert Co.* v. *Kent*, 2007 U.S. S. Ct. Briefs LEXIS 1867, at *42 (Nov. 28, 2007); *see, e.g.*, *Estée Lauder*, 727 F. Supp. at 5. Congress also authorized FDA to *forgo* enforcement—even in the face of an undisputed violation—where the Agency "believes that the public interest will be adequately served" thereby. 21 U.S.C. 336; *United States* v. *Sullivan*, 332 U.S. 689, 694 (1948).[5] This Court has recognized that the FDCA "commit[s] complete discretion to [FDA] to decide how and when" the statute's enforcement tools "should be exercised," *Heckler* v. *Chaney*, 470 U.S. 821, 835 (1985), and that these decisions are unreviewable, *id.* at 837-38.

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[5] *See, e.g.*, 78 Fed. Reg. 57397, 57398 (Sept. 18, 2013) ("FDA may exercise enforcement discretion to permit" certain ophthalmic drugs "that [are] not the subject of an approved NDA to be marketed," provided that they "do[] not constitute a hazard to health" or "bear claims for serious disease conditions").

From the beginning, the FDCA has provided that "all . . . proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States." 21 U.S.C. 337(a). Thus, the FDCA "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance." *Buckman*, 531 U.S. at 349 n.4 (citing § 337(a)). The entrustment of enforcement authority to FDA was the very "heart of" the FDCA regime. *Hynson, Westcott & Dunning*, 412 U.S. at 627.

It is not difficult to see why. Only FDA has the "expertise" and "specialization" required to administer the statute's often-technical provisions. *Weinberger* v. *Bentex Pharms., Inc.*, 412 U.S. 645, 652-54 (1973). Only FDA has the broad perspective needed to ensure "[u]niformity and consistency" in the statute's application. *Ibid.* Only FDA has the ability to "to decide which of the [many] statutorily prescribed remedies, *if any*," best "fit [a given] violation and the overall purposes of the Act." Br. of the United States as *Amicus Curiae* on the Merits in *Buckman*, 2000 U.S. S. Ct. Briefs LEXIS 504, at *41-42 (Sept. 13, 2000) (citing *Chaney*, 470 U.S. at 831) (emphasis added). And only FDA can ensure that the statute is applied in the broad public interest, rather than to advance the private interests of litigants in a particular action. *See ibid.* (citing *Pennsylvania* v. *Nelson*, 350 U.S. 497, 507-08 (1956)).

2. The California Regime

a. The Sherman Law

After the FDCA's enactment, many states moved to "assimilat[e] and adopt[]" its provisions. J. Albert Hutchinson, *Enforcement of California Food and Drug Acts*, 5 Food Drug Cosm. L.J. 387, 387 (1950). California did so in 1939. *Ibid.*; *see also* Wayne D. Hudson, *California's Part in Food and Drug Law*, 9 Food Drug Cosm. L.J. 579, 579 (1954) (noting that California's food-and-drug laws were "modeled after the [FDCA] of 1938").

One example is California's Sherman Food, Drug, and Cosmetic Law ("Sherman Law"), 1970 Cal. Stat. 1573. The Sherman Law contains definitions of "drug" and "cosmetic" substantially identical to the FDCA's. Cal. Health & Saf. Code 109925, 109900. Like the FDCA, the Sherman Law prohibits the sale of a "new drug" unless "a new drug application has been approved for it . . . under Section 505 of the federal act [*i.e.*, the FDCA]." *Id.* § 111550.[6] And as with

[6] Alternatively, § 111550 purports to allow the sale of a "new drug" if "the [California State] [D]epartment [of Health] has approved a new drug . . . application" for it. However, the state-level NDA process described in § 111550 is a dead letter: it was undisputed in both the district court and the Federal Circuit that California has never approved an NDA; that it has no mechanism for doing so; and that it uniformly relies on the FDA approval process. C.A. App. 2208. *See Jones* v. *Rath Packing Co.*, 430 U.S. 519, 526 (1977) (in preemption cases, courts must "consider the relationship between state and federal

the FDCA, the Sherman Law provides only for governmental enforcement. *Id.* § 111840.

b. The Unfair Competition Law

Under California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code 17200, any act by a business entity that violates any other law—federal, state or local—is deemed "unfair competition" and made privately actionable. *Cel-Tech Commc'ns, Inc.* v. *L.A. Cellular Tel. Co.*, 973 P.2d 527, 539-40 (Cal. 1999) ("[The UCL] 'borrows' violations of other laws and . . . [makes them] independently actionable."); *accord Webb* v. *Smart Document Solutions, LLC*, 499 F.3d 1078, 1082 (9th Cir. 2007). Thus, the UCL purports to provide a universal private right of action under California law for violation of any statute.

C. Proceedings Below

1. In The District Court

After unsuccessfully lobbying FDA to deem RevitaLash a "drug," Allergan turned its efforts to federal court. In July 2009, Allergan amended its complaint in a preexisting patent action against Athena (and several other eyelash-conditioner manufacturers) to add a claim under California's UCL. The conduct that allegedly constituted "unfair competition" was Athena's sale of RevitaLash without "new drug" approval. Allergan explicitly affirmed that its "UCL claim [was] *not* based on misrepresen-

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laws as they are . . . applied, not merely as they are written").

tation or deception," or on a purported lack of safety. C.A. App. 498 (emphasis in original). Rather, Allergan explained, its claim "ar[ose] purely as a result of Athena's failure to obtain an approved new drug application." C.A. App. 500.

Athena moved for judgment on the pleadings, arguing that Allergan's "lack-of-FDA-approval" claim was an impermissible, back-door attempt to enforce the FDCA. In its opposition, Allergan emphasized the roundabout way in which its claim was pleaded: Allergan used (1) California's UCL to "borrow" Athena's alleged violation of (2) Section 111550 of California's Sherman Law, which incorporates by reference (3) Section 505 of the FDCA, the requirement that all "new drugs" be approved by FDA. Allergan did not dispute that its UCL claim would be impliedly preempted if it had omitted step (2) of this sequence. But in Allergan's view, the Sherman Law detour somehow dispelled any preemptive conflict.

The district court agreed with Allergan. It further held that no deference to FDA was appropriate, concluding that "[a]ny level of expertise required" to apply FDA's "intended use" standard "is not the type that is beyond the Court or more likely found in an administrative agency." Pet. App. 92a.

The district court granted summary judgment to Allergan, holding that all RevitaLash eyelash conditioners (past, present, and future) are "drugs" under FDA's "intended use" regulation. In reaching this determination, the district court cited (1) the fact that RevitaLash contains a prostaglandin analog; (2)

long-discontinued marketing claims by Athena; (3) the "pricing" of RevitaLash (apparently under the impression that cosmetics are never expensive); and (4) the fact that RevitaLash is "applied . . . at night . . . over a period of weeks" (apparently believing that cosmetics are never so applied). Pet. App. 71a-74a. The court disregarded both (1) FDA's statements about the Agency's view of RevitaLash's "intended use," and (2) the fact that FDA had refused to take any action against Athena.

In light of its conclusion that Athena's products are "drugs" under the FDCA's "intended use" standard, the district court held that Athena had violated § 505 of the FDCA; that Athena had therefore also violated § 111550 of the Sherman Law, which incorporates § 505 by reference; and that *this Sherman Law violation* was actionable under California's UCL. Pet. App. 75a-76a. To remedy this "unfair competition," the district court permanently enjoined the sale of RevitaLash (or any similar Athena product) *anywhere in the United States*, unless and until Athena submits an NDA and receives "new drug" approval from FDA. Pet. App. 43a.

2. In The Federal Circuit

The Federal Circuit affirmed in part and reversed in part.[7]

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[7] Jurisdiction was proper in the Federal Circuit—as that court held—because Allergan's original complaint contained patent claims, such that the district court's jurisdiction arose under 28 U.S.C. 1338. Pet. App. 4a-6a; *see*

Athena argued that Allergan's invocation of the Sherman Law was a red herring: whether Athena's liability was premised on its obligation to seek FDA approval under the FDCA, or the very same obligation incorporated into state law, the claim involved Athena's "dealings with the FDA," *Buckman*, 531 U.S. at 347, and "[c]ould not exist absent the federal regulatory scheme established by the FDCA," *Riley* v. *Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009) (citing *Buckman*, 531 U.S. at 352-53).

The Federal Circuit was unmoved. It began by invoking a "[pre]sumption" against preemption, Pet. App. 9a, even though *Buckman* unanimously held that "no presumption against pre-emption obtains" where a claim concerns the "inherently federal" FDA-approval process. 531 U.S. at 347-48.

The Federal Circuit then concluded that Allergan's claim could "not [be] an obstacle to realizing federal objectives" because the Sherman Law "parallel[s] . . . the FDCA." Pet. App. 9a. Because Allergan was ostensibly raising a "parallel" claim, the Federal Circuit did not analyze how such claims under state law impact FDA's administration of the federal scheme "[a]s a practical matter," as the *Buckman* Court had done. 531 U.S. at 350.

Holmes Grp., Inc. v. *Vornado Air Circulation Sys.*, 535 U.S. 826, 829, 834 (2002) ("[T]he Federal Circuit's jurisdiction is fixed with reference to that of the district court, and turns on . . . whether a patent-law claim appear[ed] on the face of the plaintiff's well pleaded complaint.").

After rejecting Athena's preemption defense and affirming the district court's grant of summary judgment, the Federal Circuit nevertheless held that a *nationwide* injunction was an overbroad remedy, and narrowed the injunction to California. It reasoned that (1) the UCL does not apply extraterritorially; (2) under the Commerce Clause of the U.S. Constitution, the UCL *could not* so apply; and (3) a nationwide injunction would "usurp the discretionary enforcement authority of the FDA." Pet. App. 15a-18a. The Federal Circuit did not explain why a statewide injunction—or a patchwork of 50 such injunctions—would *not* "usurp" FDA's authority.

REASONS FOR GRANTING THE PETITION

This case merits review for three reasons. *First*, by allowing a state-law tort claim premised on a party's alleged failure to obtain FDA approval, the Federal Circuit created a direct split with decisions of the Second, Sixth, and Ninth Circuits (and many district courts) that have held such claims impliedly preempted under FDCA § 337(a). *Second*, the decision below epitomizes the deep and longstanding confusion concerning the proper scope of § 337(a) preemption—an issue relevant to all litigation concerning FDA-regulated articles. *Third*, by allowing a private suit to ban a product in one state, the decision below poses an unprecedented threat to the uniformity of the federal regulatory scheme and invites a tidal wave of disruptive "parallel" litigation.

I. THE DECISION BELOW CREATES A DIRECT CIRCUIT SPLIT REGARDING THE VIABILITY OF STATE-LAW "LACK-OF-FDA-APPROVAL" CLAIMS.

Unlike the Federal Circuit, at least three circuit courts of appeal, and numerous district courts, have concluded that § 337(a) *does* bar private suits under state unfair-trade-practices statutes based on alleged failure to obtain FDA approval.[8]

In *PDK Labs, Inc.* v. *Friedlander*, 103 F.3d 1105 (2d Cir. 1997), the defendant sold products it claimed were "dietary supplements" under the FDCA. The plaintiff argued—as Allergan does here—that the products "contain[ed] ingredients which render[ed] them 'new drugs' for which FDA approval is required." *Id.* at 1111-12 & n.6. Just as here, FDA "ha[d] never objected to [defendant's] products or advertising, despite access to both." *Ibid.* The plaintiff sued under (*inter alia*) Georgia's Deceptive Trade Practices Act. *Id.* at 1107. The Second Circuit concluded that, notwithstanding the claims' state-law framing, the plaintiffs' "insistence that [the] products [were] sold without proper FDA approval" was an "impermissible" attempt "to privately enforce alleged violations of the FDCA." *Id.* at 1113 (citing § 337(a)).

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[8] The Federal Circuit purported to apply Ninth Circuit law. Pet. App. 6a. However, the Federal Circuit cited no Ninth Circuit precedent in support of its preemption holding, which it purported to derive directly from decisions of this Court. Pet. App. 9a-11a.

Loreto v. *P&G*, 515 F. App'x 576 (6th Cir. 2013), involved a similar claim. There, the plaintiff alleged that "[i]n order . . . to properly sell [its] Products in interstate commerce, [defendant] was . . . required to submit a 'new drug' application and have it approved by the FDA." *Loreto* v. *P&G*, 737 F. Supp. 2d 909, 915 (S.D. Ohio 2010), *rev'd in part*, 515 F. App'x 576. The lack of such approval, the plaintiffs alleged, caused the products' sale to violate several state unfair-trade-practices statutes. *Id.* at 909, 916-18; 515 F. App'x at 579. Relying on *Buckman*, the Sixth Circuit held this claim "clearly preempted." *Id.* at 579. The teaching of *Buckman*, the court observed, is that a state-law claim—however pleaded—is barred if, "were it not for the federal regulatory scheme the FDCA created, there would have been no [valid] claim." *Id.* at 579.

PhotoMedex, Inc. v. *Irwin*, 601 F.3d 919 (9th Cir. 2010), presented an analogous claim involving a medical device. Under the FDCA, new devices need not be pre-cleared for sale if FDA has cleared a previous version, and the device has not "significantly changed." *Id.* at 925-26. The plaintiff alleged that the defendant's device "varied enough from [the] cleared [version] to require a separate [FDA] filing," *id.* at 927-28. As in this case, FDA "ha[d] not itself concluded that there was [any] violation," even though the plaintiff had lobbied for such a result. *Id.* at 924, 926-27. The Ninth Circuit held that just as "Section 337(a) of the FDCA bars private enforcement of th[at] statute," it "also limits the ability of a private plaintiff to pursue claims under state law theories

where such claims collide with the exclusive enforcement power of the federal government." *Id.* at 924 (quoting *Buckman*). A private plaintiff, the court concluded, "is not permitted to circumvent the FDA's exclusive enforcement authority by seeking to prove" that a device required FDA clearance "when the FDA did not reach that conclusion." *Id.* at 928; *accord Perez* v. *Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013) ("whether [approval] of [a] device [is] required" is a determination that "rest[s] within the enforcement authority of the FDA, not this Court").

Many district courts have similarly held "lack-of-FDA-approval" claims preempted, as "the FDA, not [a] district court, must determine whether a drug is legally on the market." *Autin* v. *Solvay Pharms., Inc.*, 2006 U.S. Dist LEXIS 19507, at *2-3, *10-11 (W.D. Tenn. Mar. 31, 2006) (barring state unfair-trade-practices claim that product "cannot be sold legally because it is a new drug without FDA approval"); *accord Sadler* v. *Advanced Bionics, Inc.*, 929 F. Supp. 2d 670, 685 n.20 (W.D. Ky. 2013); *Reeves* v. *PharmaJet, Inc.*, 846 F. Supp. 2d 791, 794-98 (N.D. Ohio 2012); *Purchase* v. *Advanced Bionics, LLC*, 896 F. Supp. 2d 694, 696 (W.D. Tenn. 2011); *Braintree Labs, Inc.* v. *Nephro-Tech, Inc.*, 1997 U.S. Dist. LEXIS 2372, at *4, *22-24 (D. Kan. Feb. 26, 1997).

The decision below created a direct split with this unbroken line of authority. This Court should grant certiorari and restore that prior consensus.[9]

II. THE DECISION BELOW ILLUSTRATES THE DEEP CONFUSION REGARDING THE SCOPE OF IMPLIED PREEMPTION UNDER SECTION 337(a).

Although the lower courts were unanimous until now that "lack-of-FDA-approval" claims are impliedly preempted, there is a deep and longstanding division about the proper test for implied preemption under § 337(a).

That provision, again, states that "[a]ll . . . proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." It goes without saying that § 337(a) precludes private claims under the FDCA itself. In *Buckman*, however, this Court held unanimously that § 337(a) does more than just that: it also "impliedly pre-empt[s]" at least *some* claims "under

[9] Allergan argued below that some of these cases are distinguishable because Allergan's claim arose under a *state statute* that incorporates the FDCA by reference, rather than the FDCA itself. This is a distinction without a difference: *any* claim premised on lack of FDA approval, whatever the statutory hook, implicates the federal approval process, and could not exist "were it not for the federal regulatory scheme the FDCA created." *Loreto*, 515 F. App'x at 579. Indeed, *Buckman* itself involved a *state-law* claim of alleged misconduct during the FDA-approval process—not a direct claim for violation of the FDCA. *Post* at 24.

state tort law." *Id.* at 343, 348. Which claims fall within § 337(a)'s preemptive ambit remains an unsettled question.

A. This Court's Decisions In *Buckman* And *Mensing*

In *Buckman*, the plaintiffs sought damages for personal injuries caused by a medical device. As in this case, their claim "d[id] not depend on any showing that the device was somehow defective, or falsely advertised." Br. of the United States as *Amicus Curiae* in Support of Certiorari in *Buckman*, 1999 U.S. S. Ct. Briefs LEXIS 1003, at *26 (June 7, 1999). Instead, the plaintiffs asserted that the device was unlawfully on the market because the defendants misrepresented its "intended use" during the FDA-approval process. *See In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817 (3d Cir. 1998), *rev'd sub nom. Buckman* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); *Buckman*, 531 U.S. at 346-47.

Importantly, although the FDCA imposes a duty of truthfulness on applicants, the plaintiffs' so-called "fraud-on-the-FDA" claim *did not invoke* that federal statutory duty, directly or indirectly. *Bone Screw*, 159 F.3d at 821-22. Rather, the plaintiffs based their claim entirely on a *state common-law* duty not to make false statements to one party that foreseeably cause injury to another party. *Id.* at 822, 826-27 (citing RESTATEMENT (SECOND) TORTS § 310); *see Buckman*, 531 U.S. at 343 ("Plaintiffs s[eek] damages from petitioner under state tort law.").

The Court held that this claim "conflict[ed] with, and [was] therefore impliedly pre-empted by," the FDCA. *Buckman*, 531 U.S. at 348. The conflict was not one of *substantive* standards: both the FDCA and state law purportedly required truthful disclosures to FDA. Instead, the conflict was with FDA's *singular enforcement role*—as underscored by the Court's repeated citations to § 337(a). *See id.* at 349 n.4 (citing § 337(a)); *id.* at 352 (same). As this Court explained, "in practice," state-law claims like the plaintiffs' would have the same deleterious consequences that Congress desired to avoid when it expressly barred private plaintiffs from meddling with FDA's enforcement choices. *Id.* at 347-51.[10]

More recently, in *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567 (2011), the Court made clear that implied preemption under § 337(a) goes beyond the specific facts of *Buckman*. *Mensing* was a classic state-law failure-to-warn case. However, under the federal scheme regulating generic drugs, the defendant manufacturers could not have changed their labels to include the warnings that state law required without FDA's authorization. The ultimate question was whether this scenario resulted in implied "impossibil-

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[10] *Cf. Astra USA, Inc.* v. *Santa Clara Cnty.*, 131 S. Ct. 1342, 1348 (2011) (where Congress barred private actions under the Public Health Services Act, state-law claims that "incorporate [those federal] statutory obligations" are "in essence . . . suit[s] to enforce the statute," and are "inconsistent with the legislative scheme to the same extent" as claims "directly under the statute").

ity" preemption. But *Buckman* (and, thus, "purposes and objectives" preemption under § 337(a)) played a key role in the Court's analysis.

In analyzing whether the manufacturers could simultaneously comply with both federal and state law, the Court deemed it irrelevant that FDA might have authorized a label change if the manufacturers had sought its permission. The Court cited *Buckman* for the broad proposition that the FDCA "preempt[s] a state tort-law claim based on *failure to properly communicate* with the FDA." *Id.* at 2578 (emphasis added). Stated otherwise, a manufacturer's decision whether to approach FDA and "ask[] for [its] help" is simply "not a matter of state-law concern." *Id.* at 2581. Because the manufacturers could not meet their state-law duty without FDA authorization, and because *Buckman* places the decision whether to approach FDA beyond the states' purview, a finding of impossibility was compelled. *Ibid.*

B. The Lower Courts' Split Concerning Section 337(a)'s Preemptive Effect

In the view of Athena and others, § 337(a) squarely preempts "lack-of-FDA-approval" claims. *See* Steven Boranian, "Federal Circuit Bats an Eye at FDCA Preemption," Drug and Device Law, Jan. 10, 2014, http://druganddevicelaw.blogspot.com/2014/01/federal-circuit-bats-eye-at-fdca.html ("[Athena] had a point. . . . Congress gave the FDA exclusive authority to determine whether a product should be regulated as a drug, and that prerogative cannot co-exist with . . .

thousands of courts applying state law[] undertaking the same task.").

However, lower-court views of § 337(a) preemption "have diverged." Matthew A. Reed, *What's the Implication? Courts and the Scope of Implied Medical Device Preemption*, 27 Wash. Legal Found. Legal Backgrounder 22 at 3 (Nov. 16, 2012). Commenters have described "the extent of" § 337(a) preemption as an issue "fraught with controversy," Catherine M. Sharkey, *The Fraud Caveat to Agency Preemption*, 102 Nw. U. L. Rev. 841, 856-57 (2008), and noted that the "judicial disarray" in this area "has caused confusion and a lack of predictability for both injured parties and . . . manufacturers," Jean Macchiaroli Eggen, *Navigating Between Scylla and Charybdis: Preemption of Medical Device "Parallel Claims*," 9 J. Health & Biomed. L. 159, 160-61, 208 (2013).

Some lower courts, viewing *Buckman* as a one-off decision, apply § 337(a) preemption "solely to fraud-on-the-FDA claims." J. David Prince, *Medical Device Law: The Puzzle of Parallel Claims, Preemption, and Pleading the Particulars*, 39 Wm. Mitchell L. Rev. 1034, 1074-75 (2013). Here, for example, the Federal Circuit purported to distinguish *Buckman* on the grounds it "involved a claim based on fraud before the FDA." Pet. App. 10a. The Ninth Circuit took a similarly narrow view of § 337(a) in *Stengel* v. *Medtronic, Inc.*, 704 F.3d 1224, 1230 (9th Cir. 2013) (en banc); *see* Prince, *supra*, 39 Wm. Mitchell L. Rev. at 1076-77 ("*Stengel* . . . clearly stands for the proposition that state-law claims are not impliedly preempt-

ed unless they are specifically a fraud-on-the-FDA claim.").[11]

Indeed, in a widely-cited decision that the Federal Circuit relied upon below, the California Supreme Court effectively denied the existence of § 337(a) preemption altogether:

> The crux of defendants' preemption argument is that plaintiffs' private state claims [under California's UCL] are precluded because they improperly seek to enforce the FDCA in violation of section 337(a). . . . [But § 337(a)], by its very terms, only implicates efforts to enforce *federal* law. What section 337 does *not* do is limit, prohibit, or affect private claims predicated on *state* laws.

Farm Raised Salmon Cases, 175 P.3d 1170, 1181-82 (Cal. 2008), *cert. denied sub nom. Albertson's Inc. v. Kanter*, 555 U.S. 1097 (2009).

By and large, these courts' cramped view of § 337(a) preemption stems from a misunderstanding of *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996) and *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312 (2008). *Lohr* addressed whether a traditional state-law product-liability claim was *expressly* preempted under 21 U.S.C. § 360k, a clause added to the FDCA by the

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[11] *Accord Bausch* v. *Stryker Corp.*, 630 F.3d 546, 557 (7th Cir. 2010); *Howard* v. *Zimmer, Inc.*, 711 F.3d 1148, 1150-52 (10th Cir. 2012).

Medical Device Amendments of 1976. Because the terms of that clause bar only state-law device requirements "different from, or in addition to" federal requirements, the Court logically concluded that "[n]othing *in § 360k* denies [states] the right to provide a traditional damages remedy for violations of common-law duties [that] parallel federal requirements." *Id.* at 495 (emphasis added). *Riegel* reiterated the same conclusion. 552 U.S. at 330.

Many lower courts—including the Federal Circuit below—have construed *Lohr* and *Riegel* as "an across-the-board holding that there [is] no preemption" of "parallel" claims "under any . . . categor[y]" of preemption. *Stengel*, 704 F.3d at 1228, 1230; *accord Bass* v. *Stryker Corp.*, 669 F.3d 501, 514 (5th Cir. 2012) (interpreting *Riegel* as "unequivocally" precluding even implied preemption of "parallel" claims); *Farm Raised Salmon*, 175 P.3d at 1181-82 (same). Under that interpretation of *Lohr* and *Riegel*, *Buckman*—a case where a "parallel" claim *was* deemed impliedly preempted—would indeed appear to be an aberration, limited to its specific facts.

But this reading of *Lohr* and *Riegel* is wrong. In *Buckman*, this Court cautioned that *Lohr* "did not . . . address . . . *implied* preemption." 531 U.S. at 353 (emphasis added). Nor was implied preemption at issue in *Riegel*. 552 U.S. at 345 (Ginsburg, J., dissenting) (noting that respondent "relie[d] exclusively on § 360k[] and d[id] not argue [implied] preemption"). Thus, as this Court has unanimously recognized, *Lohr* and *Riegel* "do[] not and cannot stand for the proposition" that parallel claims always—or even

generally—escape *implied* preemption under § 337(a). *Buckman*, 531 U.S. at 353; *cf. Arizona* v. *United States*, 132 S. Ct. 2492, 2505 (2012) ("[T]he existence of an express pre-emption provision does not . . . impose a 'special burden' that would make it more difficult to establish [implied] preemption of laws falling outside the clause.").

Other lower courts, unburdened by this misreading of *Lohr* and *Riegel*, have taken a diametrically opposite approach to § 337(a) preemption. These courts read *Buckman* "broadly" as preempting "*any* private [state-law] action that incorporates a violation of an FDA regulation." Prince, *supra*, 39 Wm. Mitchell L. Rev. at 1072 (emphasis added). *See, e.g.*, *Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) ("[T]he plaintiff must not be suing *because* the [defendant's] conduct violates the FDCA," as "such a [state-law] claim would be impliedly preempted"). These cases reason that private plaintiffs "cannot make an end run around" § 337(a) "by recasting violations of the FDCA as violations" of "parallel" state laws. *McClelland* v. *Medtronic, Inc.*, 944 F. Supp. 2d 1193, 1200 (M.D. Fla. 2013).[12]

Still other courts have staked out intermediate positions. These courts do not limit § 337(a) preemp-

[12] Allergan itself successfully advanced this maximalist position when its own ox was being gored. *See Goldsmith* v. *Allergan, Inc.*, 2011 U.S. Dist. LEXIS 6233 (C.D. Cal. Jan. 13, 2011), *subsequent order at* 2011 U.S. Dist. LEXIS 80998 (C.D. Cal. May 25, 2011) (finding California UCL claim against Allergan impliedly preempted).

tion to "fraud-on-the-FDA" claims, but neither do they extend it to *all* state-law claims involving FDCA violations. The precise tests that these courts have adopted depend on which of several passages in *Buckman* they deem authoritative.

The Fifth Circuit, for example, has held that "the dispositive factor" for implied preemption under § 337(a) is whether a state-law claim "involve[s] the relationship between the federal regulator [*i.e.*, FDA] and the regulated entity." *Lofton* v. *McNeil Consumer & Specialty Pharms.*, 672 F.3d 372, 377 (5th Cir. 2012). *Cf. Buckman*, 531 U.S. at 347 ("[T]he relationship between a federal agency and the entity it regulates is inherently federal in character").

Pointing to different language in *Buckman*, the Ninth Circuit has articulated another test, where "[t]he key factor" is whether "'the existence of . . . federal enactments is a critical element in [the plaintiff's] case.'" *Nathan Kimmel* v. *DowElanco*, 275 F.3d 1199, 1206 (9th Cir. 2002) (quoting *Buckman*, 531 U.S. at 353); *accord Perez*, 711 F.3d at 1119-20.

And relying on still other language in *Buckman*, the Sixth Circuit has framed a slightly different test:

> [To avoid preemption, t]he conduct on which the claim is premised must be the type of conduct *that would traditionally give rise to liability under state law*—and that would give rise to liability under state law even if the FDCA had never been enacted.

Loreto, 515 F. App'x at 579 (emphasis added and internal quotation marks omitted); *accord Blankenship* v. *Medtronic, Inc.*, 2014 U.S. Dist. LEXIS 39063, at *10-11, *23-24 (E.D. Mo. Mar. 25, 2014); *Caplinger* v. *Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1214-15 (W.D. Okla. 2013); *cf. Buckman*, 531 U.S. at 353 ("[P]laintiffs . . . [are] not . . . relying on traditional state tort law which had predated the federal enactments in question").

Athena submits that the cramped, "fraud-on-the-FDA-only" view adopted by the Federal Circuit cannot be correct. Nothing in the text of § 337(a) or this Court's precedents suggests such an arbitrary limitation to that provision's preemptive effect. Whatever the proper test, this case provides an excellent vehicle to resolve this deep and troublesome division in the lower courts.

III. THIS CASE RAISES ISSUES OF NATIONAL IMPORTANCE WARRANTING THIS COURT'S IMMEDIATE ATTENTION.

The extent of implied preemption under § 337(a) is a question of profound national importance. It potentially bears on *every* state-law suit involving an FDA-regulated article—and such articles "account[] for 25 cents of every dollar spent by [U.S.] consumers." John P. Swann, *FDA's Origin*, http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm. But *this particular* § 337(a) preemption case raises especially critical concerns warranting immediate review and reversal.

A. The Decision Below Is An Unprecedented Threat To The Uniformity And Consistency Of The FDCA Regime.

In enacting the FDCA, Congress intended to replace the existing patchwork of state-by-state regulation with a nationwide approach. Without doubt, "[u]niformity and consistency" were key objectives of the new regime. *Bentex Pharms.*, 412 U.S. at 652-54; *see United States* v. *Regenerative Scis., LLC,* 741 F.3d 1314 (D.C. Cir. 2014) ("[t]he FDCA enact[ed] a comprehensive, uniform regulatory scheme"); H.R. Rep. No. 59-2118, at 5-6 (1906) ("One of the hoped for good results of a national [food and drug] law is . . . a uniformity of laws and regulations.").

All private quasi-enforcement suits hinder Congress's desire for uniformity and consistency, but some suits pose much greater threats than others. In particular, before now, successful private "parallel" litigation was limited to claims for *money damages*. *See Levine*, 555 U.S. at 579 (parallel "[s]tate tort suits . . . serve a distinctly *compensatory* function" (emphasis added)); *Lohr*, 518 U.S. at 495 ("[n]othing in § 360k denies [states] the right to provide a *traditional damages remedy* for . . . parallel [claims]" (emphasis added)). Occasional state-law damages suits make it more burdensome for manufacturers to operate nationwide. *See Buckman*, 531 U.S. at 350. But they do not pose categorical obstacles to national uniformity.

Suits like this one do. The Federal Circuit permitted an unprecedented private claim *to determine an*

article's regulatory classification under FDA's "intended use" standard and, on that basis, *to ban an article's sale* in one state. As a result of the judgment below, RevitaLash (and any similar product Athena may introduce in the future) is an unlawful "drug" for purposes of FDA's intended-use regulation within the borders of California. But FDA regards RevitaLash as a lawful "cosmetic" under that same regulation, and permits it to be sold everywhere else. "Parallel" litigation of this sort is fundamentally different from a "parallel" claim for damages to redress personal injury, and it poses a vastly greater threat to national uniformity. *Cf. Mutual Pharm. Co.* v. *Bartlett*, 133 S. Ct. 2466, 2488, 2491 (2013) (Sotomayor, J., dissenting).

To make matters worse, several other companies who were co-defendants in the district court remain free to sell *their* eyelash conditioners—which Allergan had also alleged to be unapproved "drugs"—everywhere in the United States. This disparity is not attributable to any differences between their products and Athena's, but to Allergan's strategic decision to settle with some parties and not others. Thus, even within a single state, this sort of private litigation creates arbitrary, non-uniform outcomes repugnant to the FDCA's objectives. *Cf. Bentex Pharms.*, 412 U.S. at 653 (rejecting a construction of the FDCA that would "require[] compliance by one manufacturer while his competitors marketing similar [articles] remain free to violate the Act").

B. The Decision Below Invites A Wave Of Novel And Usurpative Private Lawsuits.

Before now, the scope of "parallel" litigation has been cabined in another important way: such claims have invariably required an allegation (and, ultimately, proof) that the challenged article was *actually defective, harmful, or misrepresented*. *See, e.g.*, *Levine*, 555 U.S. at 555 (drug with inadequate warning caused loss of plaintiff's arm); *Lohr*, 518 U.S. at 481 (defective pacemaker caused "heart block" requiring surgery); *Farm Raised Salmon*, 175 P.3d at 1173 (deceptive colorants "caused consumers to believe farmed salmon [was] wild salmon").

No longer. The Federal Circuit has allowed an unprecedented private claim that is "wholly independent of" any consumer harm, and is based *entirely* on a party's alleged failure to procure FDA preapproval. C.A. App. 498. In so doing, the Federal Circuit has opened a Pandora's box of "parallel" claims that, if not immediately closed, threatens to clog the courts, undermine FDA's policy judgments, and perhaps even endanger lives.

Take, for example, "off-label" promotion of drugs and devices. As this Court has noted, "off-label" *use* of such articles—*i.e.*, use for other than FDA-approved indications—is lawful, ubiquitous, and often medically necessary. *Buckman*, 531 U.S. at 350-51 & n.5. Yet *promoting* drugs and devices "off-label" changes their "intended use" under 21 C.F.R. 201.128 (the same regulation at issue here), and renders them "unapproved new drugs." *See* FDA, *Guid-*

ance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles, http://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm ("An approved . . . drug that is marketed for an unapproved use is an unapproved new drug with respect to that use."). The "boundary between permissible and impermissible" promotion—*i.e.*, between conduct that changes an article's "intended use" and conduct that does not—is a policy question that requires "difficult and subtle balancing." *Bone Screw*, 159 F.3d at 831 (Cowen, J., dissenting); *see* FDA, *Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information* at 3, http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf ("FDA recognizes that," under certain circumstances, "it can be in the best interest of public health for a firm to . . . [provide] information about off-label uses of [its] products").

Before now, state-law claims based on "off-label" promotion have been held preempted, because "the very concept of 'off-label' use and promotion is derived from the regulatory system imposed by . . . the FDCA." *Gavin* v. *Medtronic, Inc.*, 2013 U.S. Dist. LEXIS 101216, at *55 (E.D. La. July 19, 2013). But under the Federal Circuit's ruling, a company who convinces a court that a competitor's statements established a new "intended use" for its product can seek an injunction against such statements. Under the Federal Circuit's rationale, it would make no difference whether the allegedly off-label statements were 100% true and beneficial—or even vital—to the

public health. Nor would it matter if FDA had made a considered decision to forbear enforcement for those very reasons.

There are countless other scenarios where a manufacturer may arguably be out of compliance with the FDCA without causing any tangible injury or deception to consumers. Under the Federal Circuit's ruling, any such scenario now supports a private claim under "parallel" state law. The ability to sue without true injury will launch a slew of unnecessary and opportunistic lawsuits, and FDA's role as the centralized, expert enforcer of the federal scheme will continue in name only.

This is not idle speculation. California's courts are already swamped by a tide of lawyer-driven class actions against food manufacturers based on picayune FDCA violations, all asserted—like Allergan's claim here—as "parallel" claims under the UCL and Sherman Law. *See* Anthony J. Anscombe & Mary Beth Buckley, *Jury Still Out on the 'Food Court': An Examination of Food Law Class Actions and the Popularity of the Northern District of California*, BNA Class Action Litig. Report (July 2012), http://about.bloomberglaw.com/practitioner-contributions/jury-still-out-on-the-food-court/ (noting 170 such actions filed in California federal courts from April 2012 to April 2013 alone); Paul M. Barrett, *California's Food Court: Where Lawyers Never Go Hungry*, BusinessWeek, Aug. 22, 2013, http://www.businessweek.com/articles/2013-08-22/californias-food-court-where-lawyers-never-go-hungry. Because these cases' "parallelism" rationale has now been endorsed by a federal appeals

court, there is "nothing to prevent the craziness of California food litigation from . . . spilling over" into *all* FDA-related industries. Michelle Yeary, "A Tale of Two Decisions," Drug and Device Law, Feb. 12, 2014, http://druganddevicelaw.blogspot.com/2014/02/a- tale-of-two-decisions.html.[13]

* * *

In sum, while the lower courts have long disagreed on the preemptive scope of § 337(a), this case poses that question in an especially urgent context. This Court need not—and should not—wait to resolve this question until the disruptive and dangerous consequences of the Federal Circuit's decision have been realized.

[13] Indeed, the decision below has already spawned a copycat consumer class action—ironically, against *Allergan*—alleging that certain of its skin-care products "qualify as drugs . . . under both [the FDCA] and parallel state laws," but purportedly lack necessary "approv[al] . . . for sale." *See* Complaint, *Ruhnke* v. *Allergan, Inc.*, No. 14-420, ¶ 6 (C.D. Cal. Mar. 19, 2014).

CONCLUSION

For the above reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted.

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May 15, 2014

APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT, DATED DECEMBER 30, 2013

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2013-1286

ALLERGAN, INC., AND DUKE UNIVERSITY,

Plaintiffs-Appellees,

AND

MURRAY A. JOHNSTONE, M.D.,

Plaintiff,

v.

ATHENA COSMETICS, INC.,

Defendant-Appellant,

AND

PHARMA TECH INTERNATIONAL, INC., PRODUCT INNOVATIONS, LLC, NORTHWEST COSMETIC LABORATORIES, LLC, AND R & G BUSINESS LLC,

Defendants.

December 30, 2013, Decided

Appendix A

JUDGES: Before RADER, Chief Judge, MOORE, and WALLACH, Circuit Judges.

OPINION BY: MOORE

OPINION

MOORE, *Circuit Judge*.

Athena Cosmetics, Inc. (Athena) appeals from the district court's grant of summary judgment that Athena violated California's unfair competition law (UCL) by marketing, distributing and selling, without regulatory approval, products that qualify as drugs. Athena also challenges the court's entry of a nationwide injunction and the denial of a motion for judgment on the pleadings that the Federal Food, Drug, and Cosmetic Act (FDCA) preempts Allergan, Inc.'s (Allergan) UCL claim. We hold that the FDCA does not preempt Allergan's UCL claim and that there is no genuine dispute that the products at issue are drugs under California law, and thus *affirm* the grant of summary judgment. We also hold that the district court abused its discretion by entering an overbroad injunction, and thus *vacate* the injunction and *remand*.

BACKGROUND

The products at issue in this appeal are formulations of Athena's RevitaLash line, all of which contain a prostaglandin derivative as an active ingredient. The Food and Drug Administration (FDA) has not taken enforcement action against, or otherwise regulated, the

products at issue. Allergan sells a product called Latisse, which also contains a prostaglandin derivative. Latisse is a FDA-approved prescription drug used for the treatment of a condition that affects eyelash growth.

Allergan sued Athena for patent infringement and a violation of the UCL, California Business and Professions Code § 17200 *et seq*. Allergan alleged that Athena competed unfairly by violating, *inter alia*, California's Health and Safety Code (California Health Code) § 111550[1] by "marketing, selling, and distributing [its] hair and/or eyelash growth products without [a new drug] application approved by the FDA or California State Department of Health Services." Complaint at ¶¶ 82, 84, *Allergan, Inc. v. Athena Cosmetics, Inc.*, No. 8:07-cv-1316 (C.D. Cal. Sept. 30, 2011).

The district court denied Athena's motion for judgment on the pleadings that the FDCA preempts Allergan's UCL claim. Allergan moved for summary judgment that the products at issue qualify as new drugs that lack the requisite approval under the California Health Code, giving rise to a UCL violation. The court granted summary judgment and entered a permanent injunction. Athena appeals.

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1. "No person shall sell . . . any new drug . . . unless it satisfies either of the following: (a) It is . . . [a] new drug, and a new drug application has been approved for it and that approval has not been withdrawn or suspended under Section 505 of the [FDCA] . . . . [or] (b) The [California Health Department] has approved a new drug application for that new drug . . . ."

Appendix A

JURISDICTION

While this appeal does not present any patent issues, Allergan's amended complaint alleged infringement of three patents of which it is the exclusive licensee, including U.S. Patent No. 6,262,105. The parties did not initially contest our jurisdiction, but "every federal appellate court has a special obligation to satisfy itself . . . of its own jurisdiction." *Bender v. Williamsport Area Sch. Dist.*, 475 U.S. 534, 541, 106 S. Ct. 1326, 89 L. Ed. 2d 501 (1986) (internal quotation marks omitted). Therefore, we ordered supplemental briefing on our jurisdiction.

Athena argued that we have jurisdiction over this appeal. Sept. 20, 2013 Supp. Br. It argued that, as a result of actions in the underlying district court litigation, the parties' legal relations were altered with respect to the patent claims. *Id.* Allergan disputed our jurisdiction. Sept. 20, 2013 & Oct. 11, 2013 Supp. Brs.

We have exclusive jurisdiction over an appeal from a final decision of a district court (including one unrelated to patent issues) when "patent law is a necessary element of one of the well-pleaded claims" in the complaint. *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 809, 108 S. Ct. 2166, 100 L. Ed. 2d 811 (1988); 28 U.S.C. § 1295(a)(1). In some circumstances, a district court's dismissal without prejudice of a patent claim serves as a constructive amendment to the complaint, effectively removing the patent claim. *See Chamberlain Grp. v. Skylink Techs., Inc.*, 381 F.3d 1178, 1189-90 (Fed. Cir. 2004). We have explained, however, that "[d]ismissals

divest this court of jurisdiction only if '[t]he parties were left in the same legal position with respect to [all] patent claims as if they had never been filed.'" *Id.* at 1190 (quoting *Nilssen v. Motorola, Inc.*, 203 F.3d 782, 785 (Fed. Cir. 2000)). Moreover, "[n]either the specific rule under which the District Court dismissed the claims nor the wording of the dismissal alters the fundamental basis of our jurisdiction." *Chamberlain*, 381 F.3d at 1190.

In this case, following the district court's issuance of a Final Claim Construction Order, the parties proposed that the court grant summary judgment of noninfringement of the '105 patent, while preserving their full appellate rights regarding claim construction. *Allergan*, No. 8:07-cv-1316, ECF No. 679 (C.D. Cal. May 9, 2012). The court entered summary judgment "in accordance with the terms of the Stipulation." *Id.*, ECF No. 691 (C.D. Cal. May 29, 2012). Thereafter, pursuant to the parties' further agreement, the court dismissed all of the patent claims "without prejudice." *Id.*, ECF No. 1075 (C.D. Cal. Mar. 28, 2013).

We have jurisdiction over this case because the parties were not left in the same legal position as if the '105 patent claim had never been filed. The court's dismissal "without prejudice" merely reflects the parties' agreement that the '105 patent claim could be re-filed in future litigation between these parties. Should that occur, however, the parties will be bound by the court's summary judgment ruling—which the court did not vacate. Indeed, Allergan, whose decision it is whether to reassert the '105 patent against Athena, concedes on appeal that the summary judgment ruling "would bind the parties in future district

court litigation against each other." Oct. 11, 2013 Supp. Br. at 2. The court's dismissal of the '105 patent claim did not undo this alteration in legal status, and therefore we have jurisdiction over this appeal pursuant to 28 U.S.C. § 1295(a)(1).[2]

Analysis

Where an issue is not unique to patent law, we apply the law of the regional circuit from which the case arises. *Sulzer Textil A.G. v. Picanol N.V.*, 358 F.3d 1356, 1363 (Fed. Cir. 2004). The Ninth Circuit reviews grants of summary judgment and determinations regarding preemption *de novo*. *Engine Mfrs. Ass'n v. S. Coast Air Quality Maint. Dist.*, 498 F.3d 1031, 1035 (9th Cir. 2007). The Ninth Circuit reviews the decision to grant a permanent injunction, as well as its scope, for abuse of discretion, and underlying factual findings for clear error. *Columbia Pictures Indus., Inc. v. Fung*, 710 F.3d 1020, 1030 (9th Cir. 2013).

I. Preemption

The California Health Code incorporates various provisions of the FDCA, which does not itself allow a private right of action. *See* 21 U.S.C. § 337(a). The district court held that the FDCA did not preempt Allergan's UCL

2. Athena contends that the district court altered the legal status of the parties with respect to each of the other two patent claims. Sept. 20, 2013 Supp. Br. at 2-3. Because the change in legal status with respect to the '105 patent claim is sufficient to supply our jurisdiction, we need not address the other patents.

claim. It stated that "mentions of the FDCA throughout" its order were "referential" because "[i]n order to determine if the [California Health Code] is violated, the Court looks to whether the federal regulations incorporated therein are violated." *Allergan*, No. 8:07-cv-1316, slip op. at 4 (C.D. Cal. Oct. 11, 2012). On appeal, the parties agree that the FDCA does not expressly preempt Allergan's claim—the dispute before us concerns implied preemption.

Athena argues that the FDCA impliedly preempts Allergan's UCL claim. It contends that, under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001), a state law claim is impliedly preempted if it does not implicate a traditional state law tort principle and exists solely by virtue of a federal statute. Athena argues that Allergan's claim involves the violation of a California statute that simply incorporates FDCA provisions and is not rooted in state law tort principles.

Athena argues that the Ninth Circuit's application of *Buckman* in *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919 (9th Cir. 2010) governs this case. In that case, the court found that the plaintiff's claim based on alleged misrepresentations to the FDA about a medical device was impliedly preempted because it would have impermissibly circumvented the agency's exclusive enforcement authority. *Id.* at 926-30. Athena argues that Allergan's claim interferes with the FDA's discretionary authority whether to regulate an article in interstate commerce as a drug. Athena also argues that, under the prudential doctrine of primary jurisdiction, the district court abused

its discretion by declining to stay this case pending the FDA's determinations about the products at issue.

Allergan responds that the FDCA does not impliedly preempt its UCL claim. It argues that the FDCA contains express preemption provisions for "certain narrow topics inapplicable," including medical devices and nonprescription drugs. Resp. Br. at 17-18 (citing 21 U.S.C. §§ 360k(a), 379r). Allergan argues that there are no similar preemption provisions for prescription drugs, indicating that Congress intended that the FDCA should not preempt by implication state law claims related to this category.

Allergan argues that, under *Wyeth v. Levine*, 555 U.S. 555, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009), there is no implied preemption where simultaneous compliance with state and federal law is possible, and the state law is not an obstacle to the realization of federal goals. It argues that the California Health Code's requirements parallel the FDCA's, making compliance with both regimes possible. Allergan also argues that the district court did not abuse its discretion by retaining jurisdiction because the resolution of this case did not require the FDA's specialized knowledge.

We agree with Allergan and hold that the FDCA does not impliedly preempt its UCL claim. "[T]he purpose of Congress is the ultimate touchstone in every pre-emption case." *Id*. at 565 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996)). "'In all pre-emption cases, and particularly in those in

which Congress has legislated in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Id.* (quoting *Medtronic*, 518 U.S. at 485) (alterations omitted).

The fact that the California Health Code parallels certain FDCA provisions does not mean that it does not implicate an historic state power that may be vindicated under state law tort principles. The Supreme Court acknowledged "the historic primacy of state regulation of matters of health and safety," *Buckman*, 531 U.S. at 348, which is precisely the California Health Code's subject matter.

We do not find a clear purpose by Congress to preempt the state law claim at issue. Congress expressed its intent to preempt state-law causes of action regarding, for example, non-prescription drugs and medical devices. Allergan's contention, however, is that the products at issue must ultimately be regulated as prescription drugs—about which Congress "declined to enact such a provision." *Wyeth*, 555 U.S. at 567; *see also Farm Raised Salmon Cases*, 42 Cal. 4th 1077, 72 Cal. Rptr. 3d 112, 175 P.3d 1170, 1179 (Cal. 2008) ("[D]eference should be paid to Congress's detailed attempt to clearly define the scope of preemption under the FDCA."). Moreover, the California Health Code is not an obstacle to realizing federal objectives. To the contrary, it contains provisions that parallel the FDCA, such that the statutes have consistent goals.

Athena's principal authorities are distinguishable. *Buckman* involved a claim based on fraud before the FDA, which existed—unlike Allergan's claim—"solely by virtue of the FDCA disclosure requirements." 531 U.S. at 352-53. The Court described fraud on the FDA as—unlike state regulation of health and safety—"hardly a field which the States have traditionally occupied . . . such as to warrant a presumption against finding federal pre-emption of a state law cause of action." *Id.* at 347 (internal quotation marks omitted). *PhotoMedex* concerned an issue that does not involve federal preemption of a state law claim: "whether the FDCA limits claims under the [federal] Lanham Act." 601 F.3d at 924. The decision was limited to "particular circumstances" that are also not before us: alleged misrepresentations to the FDA about a medical device, which implicated the Medical Device Amendments of 1976 to the FDCA. *Id.* at 922, 924-28.

We see no error in the district court's determination that the FDCA does not preempt Allergan's UCL claim.

II. Summary Judgment

The California Health Code incorporates the FDCA's definition of "drugs" to include "any article other than food that is used or intended to affect the structure . . . of the body of human beings." Cal. Health Code § 109925(c); *cf.* 21 U.S.C. § 321(g)(1)(C). An article's intended use is determined based on "the objective intent of the persons legally responsible for the labeling of drugs." 21 C.F.R. § 201.128. Objective intent "is determined by such persons' expressions or may be shown by the circumstances

surrounding the distribution of the article," including "labeling claims, advertising matter, or oral or written statements by such persons or their representatives." *Id.*

The district court found no genuine dispute that Athena objectively intended to market past and present formulations of the products at issue to affect the structure of eyelashes—*i.e.*, as drugs. The court found that Athena's founder, a physician, developed an initial formulation using a prostaglandin derivative with the intent to cause users' eyelashes to grow longer and fuller. It found that Athena's marketing of subsequent formulations containing different derivatives continued to discuss eyelash growth. The court acknowledged that Athena's marketing of the most recent formulation discussed eyelash *appearance*, but concluded this did not negate an objective intent to cause *growth*.

Athena argues that there is a genuine issue of material fact about its objective intent. Athena argues that its intent should turn only on labeling and marketing materials related to its most recent formulation, and that the physical properties of the products at issue and marketing of past formulations are irrelevant. Athena contends that, within a year of its founding, it limited its marketing to claims about eyelash appearance. It argues that statements by resellers about eyelash growth do not reflect Athena's objective intent. Athena points to the testimony of a former employee that she always referred to eyelash appearance when training resellers about the products at issue. It argues that authorized resellers must acknowledge that the products at issue may only be sold as cosmetics and may not be marketed for eyelash growth.

Allergan responds that there is no genuine factual dispute that Athena objectively intends for the products at issue to be used as drugs. It argues that the physical properties and claims about past and present formulations are relevant, particularly because Athena has not materially altered the properties of, or marketing about, its various formulations. Allergan argues that Athena and its resellers advertise that the products at issue were developed by Athena's founder to treat his wife's eyelash loss. It argues that Athena's founder testified that he had reason to think the product he developed would cause eyelashes "to grow thick and long," J.A. 670-71, and sought to sell the product for that purpose. J.A. 684, 687. Allergan argues that Athena's marketing consistently references eyelash length, which depends on growth.

We agree with Allergan and hold that there is no genuine dispute that Athena objectively intends for the products at issue to be used to affect the structure of eyelashes—*i.e.*, as drugs. Athena's intent as to its line-up of products may be "derived or inferred from labeling, promotional material, advertising, or any other relevant source." *United States v. Storage Spaces Designated Nos. "8" & "49"*, 777 F.2d 1363, 1366 (9th Cir. 1985). As an initial matter, we disagree with Athena that the only relevant evidence is labeling and marketing, or that the only relevant formulation is the most recent one. Athena's website collectively refers to the RevitaLash "line-up of products," and describes formulation changes as "improve[ments]" to the intended use of "one or more of our products." J.A. 878.

Athena's marketing of the products at issue consistently discusses physical changes to eyelashes. There is no dispute that Athena made drug-related claims about an early formulation—and it never expressly disavowed such claims as it reformulated its products. Instead, the company continued to suggest that the products at issue change eyelash structure. For example, the company's website contained a message from the founder referring to his wife's "fragile, sparse and thin" eyelashes, and his development of a formula to achieve "the look of *renewed health, strength* and beauty." J.A. 875 (emphasis added). An advertisement about the most recent formulation states that the product is "both dermatologist and ophthalmologist reviewed," and describes "improved appearance" of eyelashes in the context of a "clinical study." J.A. 750; *see also* J.A. 871.

Athena's training of resellers similarly references eyelash structure. An Athena representative led a webinar for resellers in which she discussed achieving "fuller and thicker" eyelashes. J.A. 820. She discussed a "maintenance program" to retain "the desired length" after "achiev[ing] longer, fuller-looking eyelashes." J.A. 822. She stated that "eyelashes will grow naturally or with RevitaLash." J.A. 824. One reseller's marketing materials displayed a before-and-after photograph of eyelashes and promoted "dramatically thicker, longer, and lusher lashes." J.A. 960. Athena's claims invariably link eyelash appearance to physical changes caused by the products at issue.

Athena's argument that it markets *only* cosmetic benefits fails. We need not decide whether the products

at issue could *also* be cosmetics—it is sufficient to resolve this case that there is no dispute that Athena objectively intends that the products at issue be used as drugs. We therefore affirm the district court's grant of summary judgment.

III. Injunction

The district court entered a permanent injunction barring Athena from manufacturing, marketing, selling, and/or offering for sale "any and all" "eyelash growth product(s)" "anywhere within the United States." *Allergan*, No. 8:07-cv-1316, slip op. at 15 (C.D. Cal. Mar. 6, 2013). It determined that nationwide coverage was justified because Athena's UCL violation resulted from sales and advertising "throughout the United States," and "wherever the unfair competition occurs, it affects Allergan in California." *Id.* at 7-8. The court concluded that the injunction's regulation of out-of-state commerce did not violate the Commerce Clause of the United States Constitution. *Id.* at 8-10. Specifically, it found "substantial indications that other jurisdictions define 'drug'" like the California Health Code. *Id.* at 9-10. The court stated that Athena did not "demonstrate that there would be a conflict with other states' laws," and "proffer[ed] no facts to suggest that [it] would encounter contrary" law in other states. *Id.* at 7, 9-10.

Athena argues that it was an abuse of discretion for the court to issue a nationwide injunction. It argues that the injunction impermissibly reaches outside of California to remedy a violation of California law. Athena argues that

the injunction violates the Commerce Clause by regulating commerce that occurs wholly outside of California. It emphasizes that California is not part of the supply chain for the most recent formulation of the products at issue.

Allergan responds that the court did not abuse its discretion. It argues that the injunction properly applies to out-of-state conduct that causes Allergan an injury under the UCL in California. Allergan argues that the record evidence demonstrated that the injunction's nationwide scope was a practical necessity. It argues that, after Athena volunteered to stop sales of the products at issue in California before the court issued an injunction, such sales persisted within the state. Allergan also argues that there is no Commerce Clause violation because the injunction does not impose obligations on Athena that conflict with another state's law and Athena has not shown any conflict with the laws of other states. It contends that, in any event, other states could not adopt laws that are inconsistent with the California Health Code because it incorporates a regulatory floor set by the FDCA.

We agree with Athena and hold that the district court abused its discretion by entering an injunction that regulates any and all out-of-state conduct. As the California Supreme Court has stated, "[n]either the language of the UCL nor its legislative history provides any basis for concluding the Legislature intended the UCL to operate extraterritorially." *Sullivan v. Oracle Corp.*, 51 Cal. 4th 1191, 127 Cal. Rptr. 3d 185, 254 P.3d 237, 248 (Cal. 2011). The injunction impermissibly imposes the UCL on entirely extraterritorial conduct regardless of whether

the conduct in other states causes harm to California. This injunction is so broad that it would bar Athena from making its product in Idaho, distributing it from a facility in Nevada, and selling it to Connecticut consumers.

Allergan argues that *Norwest Mortgage, Inc. v. Superior Court of San Diego County*, 72 Cal. App. 4th 214, 85 Cal. Rptr. 2d 18 (1999), supports the court's imposition of a nationwide injunction in this case. It does not. In *Norwest Mortgage*, the California Court of Appeals held that UCL claims could be filed by California residents regardless of where they purchased their mortgage product and by non-California residents who purchased it in California, but not by non-California residents who purchased it outside of California (entirely extraterritorial conduct). *Id*. at 222-24. The conduct enjoined here is exactly the sort of purely extraterritorial conduct that the California Court of Appeals expressly held could not be regulated by the UCL. This injunction prevents sales that are entirely extraterritorial. It is not limited to purchases made by California residents that are being shipped into California or to sales emanating from California.

Neither the California courts nor the California legislature are permitted to regulate commerce entirely outside of the state's borders. To do so would violate the Commerce Clause, which "precludes" such extraterritorial application of state law "whether or not the commerce has effects within the state." *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336, 109 S. Ct. 2491, 105 L. Ed. 2d 275 (1989) (quoting *Edgar v. MITE Corp.*, 457 U.S. 624, 642-43, 102 S. Ct. 2629, 73 L. Ed. 2d 269 (1982)). The Commerce

Clause "dictates that no State may force an out-of-state merchant to seek regulatory approval in one State before undertaking a transaction in another." *Id.* at 337. This rule applies regardless of whether Athena can demonstrate that the laws of other states do—or even could—conflict with the UCL or the California Health Code. In short, California may, as it has in this case, conclude that its own unfair competition law has been violated, and it may prohibit any future conduct within its borders that would cause continued violation of its law. California is not permitted, however, to extend its unfair competition law to other states.[3]

The FDA—and the FDA alone—has the power and the discretion to enforce the FDCA. 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"). California does not have the authority to stand in the shoes of the FDA to determine whether Athena's sale of the products at issue amounts to the sale of an unapproved drug under the FDCA. This enforcement authority relies exclusively with the FDA. California has chosen to enact the UCL, which prevents

3. There may be instances when a court in one state may issue an injunction that applies beyond the state's boundaries such as when a federal law has been violated. The Ninth Circuit recognized such a possibility in *United States v. AMC Entertainment, Inc.*, 549 F.3d 760 (9th Cir. 2008), but nonetheless vacated the nationwide injunction because the Fifth Circuit had a different interpretation of the federal law at issue. *Id.* at 770-73. Such is not the case here. California has no obligation or right to enforce the FDCA. The only law at issue here is California's UCL.

marketing, distributing, and selling, without regulatory approval, products that qualify as drugs. While it is true that a state is not free to enact laws that do not meet the minimum requirements of the FDCA, a state is free to have no comparable state law if it chooses. The FDA does not require states to enact laws that parallel federal requirements. Thus, if other states have no laws that parallel relevant provisions of the UCL and California Health Code, there would be no mechanism at all in those states to challenge Athena's sales of the products at issue. In short, imposing the UCL on other states would violate their sovereignty, and usurp the discretionary enforcement authority of the FDA.

Allergan's reliance on Athena's purported failure to voluntarily cease sales of the products at issue in California does not justify a nationwide injunction. After summary judgment, Athena offered to voluntarily cease sales to California. An attorney for Allergan submitted a declaration stating that, after Athena's purported cessation of sales in California, she was still able to purchase a product at issue from Athena's and a reseller's website for delivery in California, as well as directly from a reseller's store in California. *See* J.A. 2729-34. This record demonstrates that these sales were isolated occurrences. Athena recognized these infractions and instituted better procedures to ensure no further sales of the products at issue in California, instructed its online resellers not to sell those products for delivery in California, and ceased to ship those products to brick-and-mortar resellers in California. *See* J.A. 3098-101. If Athena violates a properly tailored injunction, Allergan's remedy lies in a contempt

proceeding. But Athena's failure to entirely stop sales in California pursuant to its voluntary efforts cannot, as Allergan argues, justify a nationwide injunction that violates the Commerce Clause.

We vacate the permanent injunction. On remand, the district court should limit the scope of the injunction to regulate conduct occurring within California.[4]

Conclusion

We have considered the parties' remaining arguments and do not find them persuasive.

AFFIRMED-IN-PART, VACATED-IN-PART, AND REMANDED

4. Athena also argues that the district court did not make findings to support irreparable harm, and abused its discretion by drafting the injunction to cover any product containing a prostaglandin derivative applied to eyelashes. We hold that the district court made an express finding of irreparable harm that was not clearly erroneous, *see, e.g.*, J.A. 1542-43, and the scope of the products covered was not an abuse of discretion.

APPENDIX B — OPINION OF THE UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA, FILED MARCH 6, 2013

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

SACV 07-1316 JVS (RNBx)

Allergan, Inc., *et al.*

v.

Athena Cosmetics, Inc. *et al.*

March 6, 2013, Decided
March 6, 2013, Filed

Present: The Honorable James V. Selna

Karla J. Tunis	Not Present
Deputy Clerk	Court Reporter

Attorneys Present for Plaintiffs: Not Present.

Attorneys Present for Defendants: Not Present.

OPINION

Proceedings: (IN CHAMBERS) Order GRANTING Plaintiffs' Motion for Permanent Injunction

Appendix B

Against Athena Cosmetics, Inc., Cosmetic Alchemy, LLC, Lifetech Resources, LLC, and Rocasuba Inc. (Docket #s 898 & 904)

Plaintiff Allergan, Inc. ("Allergan") moves for permanent injunctions against Defendants Athena Cosmetics, Inc. ("Athena") and Cosmetic Alchemy, LLC ("Cosmetic Alchemy") (collectively, "Defendants") from engaging in unfair competition in violation of California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200 *et seq.* (Permanent Injunction Motion ("PI Motion"), Docket No. 898.) Athena and Cosmetic Alchemy timely opposed. (Athena's Injunction Opposition ("Athena PI Opp."), Docket No. 987; Cosmetic Alchemy's Injunction Opposition ("Cosmetic PI Opp."), Docket No. 945.) Allergan timely replied. (Permanent Injunction Reply to Athena ("PI Reply -- Athena"), Docket No. 1012; Permanent Injunction Reply to Cosmetic Alchemy ("PI Reply -- Cosmetic"), Docket No. 1011.) For the following reasons, the Court **GRANTS** the motion.

I. FACTUAL BACKGROUND

This Court granted partial summary judgment against Athena and Cosmetic Alchemy on Allergan's Fourth Claim for Relief on July 19 and December 20, 2012, respectively. (Athena UCL Order, Docket No. 711; Cosmetic Alchemy UCL Order, Docket No. 889.) The Court held that Athena's products (RevitaLash and its various iterations) and Cosmetic Alchemy's product (LiLash) are drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA") and California's Health and Safety Code. (Athena UCL Order,

at 16; Cosmetic Alchemy UCL Order, at 11.) The Court further held that (1) the products are new drugs under 21 C.F.R. § 310.527(a) and Cal. Health & Safety Code § 110110; (2) Defendants violate 21 U.S.C. § 355(a) and Cal. Health & Safety Code §§ 110398, 111440, and 111550 because they have not filed applications for approval of the products as new drugs or met the requirements for such classification and thus are selling misbranded products; and (3) Allergan established injury in fact under the UCL as pled because Defendants compete with Allergan and its eyelash growth drug, Latisse. (Athena UCL Order, at 16; Cosmetic Alchemy UCL Order, at 11-12.)

Allergan now requests the following permanent injunctions:

> Defendant Athena Cosmetics, Inc., its officers, agents, servants, employees, and attorneys or those in active concert or participation with them who have actual notice of the injunction shall cease and forbear from manufacturing, causing to be manufactured, marketing, selling, and/or offering for sale anywhere within the United States any and all eyelash growth product(s). This includes (1) RevitaLash, RevitaLash Enhanced, and RevitaLash Advanced; (2) any product that includes any prostaglandin, including derivatives or analogs thereof, that is marketed, promoted or otherwise directed for application directly or adjacent to the eyelid or eyelash; and/or (3) any other product marketed, promoted or otherwise directed for

eyelash growth. Defendant Athena is further enjoined from stating that its other products are the same as, similar to, more effective than, or intended for the same uses as RevitaLash, RevitaLash Enhanced, RevitaLash Advanced, or Latisse. This prohibition shall continue unless and until the FDA or another governmental agency acting within its jurisdiction approves a New Drug Application submitted by Athena for such a product, in which case Athena may manufacture, cause to be manufactured, market, sell, and/or offer for sale any product for which a New Drug Application has been approved.

Defendant Cosmetic Alchemy, LLC, its officers, agents, servants, employees, and attorneys or those in active concert or participation with them who have actual notice of the injunction shall cease and forbear from manufacturing, causing to be manufactured, marketing, selling, and/or offering for sale anywhere within the United States any and all eyelash growth product(s). This includes (1) LiLash; (2) any product that includes any prostaglandin, including derivatives or analogs thereof, that is marketed, promoted or otherwise directed for application directly or adjacent to the eyelid or eyelash; and/or (3) any other product marketed, promoted or otherwise directed for eyelash growth. Defendant Cosmetic Alchemy is further enjoined from stating that its other products are

> the same as, similar to, more effective than, or intended for the same uses as LiLash or Latisse. This prohibition shall continue unless and until the FDA or another governmental agency acting within its jurisdiction approves a New Drug Application submitted by Cosmetic Alchemy for such a product, in which case Cosmetic Alchemy may manufacture, cause to be manufactured, market, sell, and/or offer for sale any product for which a New Drug Application has been approved.

(Notice of PI Motion, Docket No. 898, at 1.)

II. LEGAL STANDARD

Injunctive relief is one of two principal remedies for violations of the UCL. *See* Cal. Bus. & Prof. Code § 17202. The standard for determining whether a permanent injunction should be granted is "essentially the same as the standard for a preliminary injunction, except that the court determines the plaintiff's success on the merits rather than the plaintiff's likelihood of success on the merits." *Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 546 n.12, 107 S. Ct. 1396, 94 L. Ed. 2d 542 (1987). The plaintiff has the burden to establish that (1) it has suffered an irreparable injury; (2) remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) the public interest would not be dis-served by a permanent injunction. *eBay, Inc. v.*

MercExchange, LLC, 547 U.S. 388, 391, 126 S. Ct. 1837, 164 L. Ed. 2d 641 (2006). The Court's "decision to grant or deny permanent injunctive relief is an act of equitable discretion." *Id.*

III. DISCUSSION

Allergan contends that it satisfies *eBay*'s four-factor test and is entitled to a permanent nationwide injunction. Defendants counter that the Seventh Amendment precludes the Court from granting injunctive relief at this stage, the scope of Allergan's proposed permanent injunction is impermissibly broad, and Allergan has not established that it merits an injunction under *eBay*. The Court addresses each argument and finds that a nationwide injunction is permitted and warranted.

A. The Seventh Amendment Does Not Preclude Injunctive Relief

Defendants argue that issuing permanent injunctive relief at this stage would deny them their Seventh Amendment right to a jury trial as to lost sales, revenue, and market share. (Athena PI Opp., at 5-7; Cosmetic PI Opp., at 5, 9-10.) The Court disagrees. "[A] summary judgment proceeding does not deprive the losing party of its Seventh Amendment right to a jury trial." *In re Slatkin*, 525 F.3d 805, 811 (9th Cir. 2008) (citation omitted). The Court previously held that Allergan established injury in fact as pled. (*See* Athena UCL Order, at 16; Cosmetic Alchemy UCL Order, at 12.) Specifically, Allergan alleged that the "unfair competition has resulted in and continues

to result in serious and irreparable injury to Allergan, including but not limited to lost sales, revenue, market share, and asset value." (Complaint ¶ 85, Docket No. 576.) Moreover, there is no right to a jury trial for this UCL claim because it arises in equity. *Smith v. Chase Mortg. Credit Grp.*, 653 F. Supp. 2d 1035, 1045 (E.D. Cal. 2009) (citing *Hodge v. Super. Ct.*, 145 Cal. App. 4th 278, 282-85, 51 Cal. Rptr. 3d 519 (2006). Thus, Allergan prevailed on the merits on a cause of action where equitable relief is appropriate, there is no genuine issue of material fact to try, and "[t]here is nothing novel" about issuing a permanent injunction now. *Cont'l Airlines, Inc. v. Intra Brokers, Inc.*, 24 F.3d 1099, 1102 (9th Cir. 1994). The parties even agreed that a trial on the UCL claim is unneeded. (*See, e.g.*, Stipulation to Reschedule Case Schedule, Docket No. 1008.) Any entitlement to other damages is not inextricably bound up with the unfair competition such that the Court should not proceed with Allergan's present request.

B. Scope of the Injunction

Athena argues that any injunction (1) should only address marketing because that would remedy the underlying UCL violation and (2) should not regulate out-of-state conduct causing alleged out-of-state injury. (Athena PI Opp., at 1.) Cosmetic Alchemy further argues that non-parties should not be bound by the injunction for independent conduct. (Cosmetic PI Opp., at 1-2.)

Appendix B

1. Conduct That Can Be Enjoined

Defendants argue that the Court should only mandate changes in the marketing, labeling, and promotion of their products to address the underlying UCL violation. (Athena PI Opp., at 1-3, 12-16; Cosmetic PI Opp., at 8-9, 12-13.) The Court disagrees.

The Court has "extraordinarily broad" authority under the UCL to craft a remedy adequate to prevent the unfair competition and unfair business practices from occurring in the future. *Hewlett v. Squaw Valley Ski Corp.*, 54 Cal. App. 4th 499, 540, 63 Cal. Rptr. 2d 118 (1997) (citations omitted). Nothing in the case law requires the injunction to be as narrow as possible. Rather, "[i]njunctive relief may be as wide and diversified as the means employed in perpetration of the wrongdoing." *Id.* (internal quotation marks and citation omitted).

Allergan's proposed injunction is not unusual; courts have enjoined the sale and distribution of unapproved, misbranded drugs. *E.g., United States v. Kasz Enters., Inc.*, 862 F. Supp. 717, 722-23 (D.R.I. 1994) (enjoining "Solution 109 Herbal Shampoo and Solution 109 Herbal Cosmetic Scalp Cleaner drugs . . . or similar products that are labeled or promoted as effective for hair growth or hair loss prevention") [hereinafter *Kasz II*]; *United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547, 575 (D.N.J. 2004) (enjoining sale of unapproved and misbranded drugs and prohibiting defendants from claiming that similar products are the same, as similar to, more effective than, or intended for the same uses as enjoined

products). The Court previously has rejected arguments that it should defer to the Food & Drug Administration ("FDA") and its practices with respect to the marketing and sale of Defendants' products. (*See* Order Denying Motion for Partial Summary Judgment on the Pleadings ("Pleadings Order"), Docket No. 685, at 10 ("Any level of expertise required to make the present determination is not the type that is beyond the Court or more likely found in an administrative agency. Nor is that expertise so great that the Court should defer to a possible agency determination.").)

More importantly, in determining that the products are drugs, the Court considered Defendants' "objective intent in promoting, distributing, and selling the product," and evaluated all "relevant source[s]" of evidence, including the physical properties of the products, *i.e.*, prostaglandin. (*E.g.*, Athena UCL Order, at 12.) The underlying UCL violation was not based only on misbranding, but on the fact that the products are new, unapproved drugs. (*See id.* at 16 (finding violations of 21 U.S.C. § 355(a) and Cal. Health & Safety Code §§ 110398, 110440, 11550).) The Court found that changing the marketing "cannot be used to circumvent the requirements of the FDCA or the California Health and Safety Code," and "the consequences of past promotional activities . . . will linger for an unknown period of time into the future." (*Id.* at 13; Cosmetic Alchemy UCL Order, at 10 (citing *United States v. Kasz Enters., Inc.*, 855 F. Supp. 534, 543 (D.R.I. 1994); *Kasz II*, 862 F. Supp. at 722).) This is especially true given consumer awareness about the products' use and effects; the nationwide demand cultivated by

Defendants and their resellers, distributors, and affiliates; and Defendants' decision not to remove prostaglandin from the products. Therefore, marketing the products as cosmetics would "not necessarily mean [they are] not [drugs]," and their sale would continue to violate the UCL absent regulatory approval. (*See* Athena UCL Order, at 15.) Similar considerations also indicate that there is no practical way to voluntarily limit sales and marketing in California absent a nationwide injunction. (*See, e.g.*, Declaration of Courtney Randall ("Randall Decl.") ¶¶ 2-14 (detailing purchase of RevitaLash Advanced in December 2012 from Athena's website), ¶¶ 15-16 (detailing purchase of RevitaLash from Athena reseller in California in December 2012); Randall Decl. Exs. 1-9, Docket No. 898-4, 5.)

Therefore, the Court finds no equitable reason to limit the injunction to cover marketing, promotional, and labeling practices and exclude the manufacture, sale, and distribution of the competing products.

2. Nationwide Injunction

Defendants argue that the geographic scope of the proposed injunction "is grossly overreaching" because the violations at issue arise only under California law, Allergan has not shown how out-of-state sales to out-of-state residents violate California law, and the UCL cannot regulate such out-of-state conduct without violating the Commerce Clause. (Athena PI Opp., at 7-8.) The Court disagrees and finds that it may issue a nationwide injunction.

Appendix B

a. *Regulating Out-of-State Conduct Through the UCL*

Although California courts generally "do not construe a statute as regulating occurrences outside the state unless a contrary intention is clearly expressed or reasonably can be inferred from the language or purpose of the statute," *Norwest Mortg., Inc. v. Super. Ct.*, 72 Cal. App. 4th 214, 222, 85 Cal. Rptr. 2d 18 (1999), the UCL clearly applies to and can regulate out-of state, domestic conduct that results in injury in California, *id.* at 223, 224 n.12 ("[O]ut-of-state conduct causing injury within the state could be enjoined, but . . . the statute [does] not regulate out-of-state conduct causing out-of-state injury."); *Speyer v. Avis Rent a Car Sys., Inc.*, 415 F. Supp. 2d 1090, 1098-99 (S.D. Cal. 2005) (citing *Norwest*, 72 Cal. App. 4th at 223-24; *Yu v. Signet Bank*, 69 Cal. App. 4th 1377, 1389, 82 Cal. Rptr. 2d 304 (1999)). Thus, because Allergan is a California resident, the Court's ability to permanently enjoin Defendants' conduct under the UCL does not end at the California border.

Athena argues that "the Court has never found Athena's sales to out-of-state residents violate any law," which weighs against using the UCL to regulate out-of-state conduct. (Athena PI Opp., at 8.) This contention is unavailing. The Court has held that Athena's sales and advertising of RevitaLash throughout the United States constitute unfair competition. That harm does not end at the California border. Each sale by Athena or its third-party resellers injures Allergan, a direct competitor.

Moreover, California's Health & Safety Code is identical to the FDCA, which sets the regulatory floor. *See Wyeth v. Levine*, 555 U.S. 555, 577-81, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009) (explaining that federal labeling standard sets a floor upon which States could build); *Chavez v. Blue Sky Natural Beverage Co.*, 268 F.R.D. 365, 375 (N.D. Cal. 2010) ("[T]he FDA has traditionally regarded state law as an additional lawyer of consumer protection that complements FDA regulation."). Defendants do not demonstrate that there would be a conflict with other states' laws, and there is no reason to believe that other states would permit Defendants' conduct.[1]

At oral argument, Athena contended that the sale of one of its products made outside of California and sold to an out-of-state resident does not violate the Sherman Law and cannot be the basis of a nationwide injunction. The point, however, is that the UCL violation--the *unfair competition* of which the Sherman Law violations are an

1. For example, Arizona, Cosmetic Alchemy's state of incorporation and location of its headquarters, has provisions related to pharmacists that use language identical to California's. *Compare* Cal. Health & Safety Code § 109925(c) *with* Ariz. Rev. Stat. Ann. § 32-1901(27) (both defining "drug" as articles "intended to affect the structure or any function of the human body"); *compare* Cal. Health & Safety Code § 111440 *with* Ariz. Rev. Stat. Ann. § 32-1965 (both prohibiting the manufacture, sale or delivery, holding or offering for sale of misbranded drugs); *compare* Cal. Health & Safety Code § 111550 *with* Ariz. Rev. Stat. Ann. §§ 32-1901(51), 32-1962 (both defining and prohibiting manufacture and sale of unapproved new drugs). New Jersey has similar statutory provisions as well. *See* N.J. Stat. Ann. §§ 24:1-1(e), 24:1-1(i), 24:5-1, 24:6a-1 (food and drugs statute).

underlying factor--justifies the nationwide injunction. That is the injury the Court is addressing, and it affects both Allergan and consumers. Wherever the unfair competition occurs, it affects Allergan in California. Therefore, there is no state-law basis to limit the injunction to California.

b. *Constitutional and Comity Concerns*

Defendants argue that a nationwide injunction would violate the Constitution because California law would be regulating out-of-state conduct in violation of the Commerce Clause. (Cosmetic PI Opp., at 14-15; Athena PI Opp., at 8-9.) Cosmetic Alchemy also believes the injunction would offend the interests of comity. (Cosmetic PI Opp., at 15-16.)

The Commerce Clause "prohibits state legislation regulating commerce that takes place wholly outside the state's borders, regardless of whether the commerce has effects within the state" and whether or not the statute's extraterritorial scope was intended by the lawmakers. *Pac. Merchant Shipping Ass'n v. Goldstene*, 639 F.3d 1154, 1177 (9th Cir. 2011) (citing *Edgar v. MITE Corp.*, 457 U.S. 624, 642-43, 102 S. Ct. 2629, 73 L. Ed. 2d 269 (1982)); *see also Healy v. Beer Inst.*, 491 U.S. 324, 336-37, 109 S. Ct. 2491, 105 L. Ed. 2d 275 (1989). However, "there is no sharply drawn line separating laws which impermissibly regulate extraterritorial commerce from those which do not." *Eric M. Berman, P.C. v. City of N.Y.*, 895 F. Supp. 2d 453, 2012 WL 4514407, at *18 (E.D.N.Y. Sept. 29, 2012). A "court must consider the practical effects of the regulatory scheme, taking into account the possibility

that other states may adopt similar extraterritorial schemes and thereby impose inconsistent obligations." *Pac. Merchant*, 639 F.3d at 1178 (citing *Healy*, 491 U.S. at 336-37). Related "considerations of comity among the states favor limited out-of-state application of exclusive rights acquired under domestic law." *Blue Ribbon Feed Co. v. Farmers Union Cent. Exch., Inc.*, 731 F.2d 415, 422 (7th Cir. 1984). The opposing party, not the moving party, must provide evidence that the injunction would result in "inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another State." *Healy*, 491 U.S. at 337; *Mujica v. Occidental Petroleum Corp.*, 381 F. Supp. 2d 1134, 1155 (C.D. Cal. 2005) ("The party asserting the applicability of the comity doctrine bears the burden of proof.").

In the injunction context,[2] the Ninth Circuit noted in 2004 that "California courts have repeatedly held that they have authority to issue injunctions which have effect beyond the borders of California, [but] this remains an open question in this circuit." *Nissan Motor Co. v. Nissan Computer Corp.*, 378 F.3d 1002, 1015 (9th Cir. 2004) (internal quotation marks and citation omitted). More recently, the Ninth Circuit explained that "[o]nce a court has obtained personal jurisdiction over a defendant, the court has the power to enforce the terms of the injunction

2. Defendants do not contend that the UCL generally and impermissibly regulates interstate commerce, only that the Court's application of the UCL to impose a nationwide injunction in this case would violate the Commerce Clause. (*E.g.*, Athena PI Opp., at 8 ("[T]he UCL cannot be used to regulate out-of-state conduct causing out-of-state injury.").

outside the territorial jurisdiction of the court, including issuing a nationwide injunction." *United States v. AMC Entertainment, Inc.*, 549 F.3d 760, 770 (9th Cir. 2008) (citations omitted). Therefore, a nationwide injunction can be based on California law, provided that the injunction does not impose inconsistent obligations on a party due to a conflict between state regulations or legislation. *See id.* at 772-73 (citing *Carson v. Here's Johnny Portable Toilets, Inc.*, 810 F.2d 104 (6th Cir. 1987); *Herman Miller, Inc. v. Palazzetti Imports & Exports, Inc.*, 270 F.3d 298 (6th Cir. 2001); Restatement (Third) of Unfair Competition § 48 cmt. c (1995)) (explaining that court should not grant nationwide relief that would cause substantial interference with established judicial pronouncements of other circuit); *Instructional Sys., Inc. v. Computer Curriculum Corp.*, 35 F.3d 813, 825-26 (3d Cir. 1994) ("[I]f the parties were subject to 'inconsistent legislation' from different states, a law's 'practical effect' might lead to a Commerce Clause violation.") (reversing district court's decision to limit application of New Jersey Franchise Practices Act to activities in New Jersey); *Herman Miller*, 270 F.3d at 326-27 (upholding nationwide injunction but excluding states that do not recognize post-mortem right of publicity).

There are substantial indications that other jurisdictions define "drug" like California, and California's Health & Safety Code mirrors the regulatory floor set by the FDCA. Other jurisdictions also impose similar regulatory requirements on the manufacture, sale, and marketing of unapproved or misbranded drugs. (*See* PI Reply -- Cosmetic, at 11 (citing statutes).) Defendants proffer no facts to suggest that they would encounter

contrary legislation or judicial precedent in other jurisdictions. There is no evidence on the record that a nationwide injunction would affront the sovereignty or law of another state, render the law of another state invalid, and negate something that has already been determined in adversary proceedings between the parties in another forum. *See AMC*, 549 F.3d at 772 (quoting *Ramirez & Feraud Chili Co. v. Las Palmas Food Co.*, 146 F. Supp. 594, 602 (S.D. Cal. 1956), *adopted and summarily aff'd*, 245 F.2d 874 (9th Cir. 1957)) (detailing court's conclusions that comity would not prevent extraterritorial exercise of jurisdictional power). Defendants may move to modify the injunction order if they uncover such a state in the future. *See Carson*, 810 F.2d at 105. This is not improper burden shifting but reflects case law that puts the onus on enjoined defendants to act. *Id.* ("As we see the equities, in the light of the parties' conduct to date and the probable trend of the law nationally, it would be fairer to require the defendant to take the litigation initiative in such a situation than to require the plaintiffs to do so."); *Mujica*, 381 F. Supp. 2d at 1155 (detailing burden in comity context). Therefore, the Court finds that a nationwide injunction based on California law would not violate the Commerce Clause or offend comity.

3. Additional Parties

Cosmetic Alchemy argues that although its "officers, agents, servants, employees, and attorneys," and others "in active concert or participation with them who have actual notice of the injunction" can be bound, these parties

cannot themselves be named and enjoined. (Cosmetic PI Opp., at 17.) Cosmetic Alchemy is correct on the law, but this has no bearing on the scope of the injunction.

Fed. R. Civ. P. 65(d) provides that "[e]very order granting an injunction" "binds only the following who receive actual notice of it by personal service or otherwise: (A) the parties; (B) the parties' officers, agents, servants, employees, and attorneys; and (C) other persons who are in active concert or participation with anyone described in [subparts (A) or (B)]." Thus, an injunction binds nonparties who have actual notice and either (1) are agents of an organization, to the extent that they are acting on behalf of the organization; (2) the alter ego of, or have an identity of interest with, a party; or (3) aid and abet a party's violation of the injunction order. *FTC v. Gill*, 183 F. Supp. 2d 1171, 1184 (C.D. Cal. 2001) (citing *Peterson v. Highland Music, Inc.*, 140 F.3d 1313, 1323-24 (9th Cir. 1998)); *FTC v. Productive Mktg., Inc.*, 136 F. Supp. 2d 1096, 1103-04 (C.D. Cal. 2001) (citations omitted). This in no way undercuts the proposition that nonparties cannot separately be "enjoined from engaging in independent conduct with respect to the subject matter of [the] suit." *Additive Controls & Measurement Sys., Inc. v. Flowdata, Inc.*, 96 F.3d 1390, 1395 (Fed. Cir. 1996) (citation omitted) (explaining that those acting in concert may be held in contempt for assisting enjoined party in violating injunction).

The boilerplate terminology Allergan proposes parrots the language of Fed. R. Civ. P 65(d). *Compare* Notice of PI Motion, at 1 ("Athena Cosmetics, Inc., its

officers, agents, servants, employees, and attorneys or those in active concert or participation with them who have actual notice of the injunction. . . .") *with Additive*, 96 F.3d at 1392-93 (detailing injunction order that, in addition to boilerplate Fed. R. Civ. P. 65(d) language as to parties, impermissibly named and enjoined specific on-parties, both individual and corporate). The injunction does not name and enjoin any particular non-party; instead, it ensures that the order cannot be circumvented through formalistic changes in corporate structure or the formation of new entities. Therefore, there is no reason to strike the language mentioning additional actors.[3]

Accordingly, the Court finds that scope of Allergan's proposed injunctions is permissible and warranted.

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3. The Court also believes it is unnecessary to add language specifying that Cosmetic Alchemy's LiBrow or Athena's other products, such as RevitaBrow or Hair by RevitaLash, are not enjoined. The language of the injunction is clear. The injunction enjoins products that are marketed, promoted, or otherwise directed for "application directly or adjacent to the eyelid or eyelash" and/or for "eyelash growth." (Notice of PI Motion, at 2-3.) The phrase "adjacent to the eyelid or eyelash" cannot reasonably be interpreted to mean that "application to the eyebrow or the hairline would be prohibited." (Athena PI Opp., at 21.) The language ensures that simple changes in marketing or instruction that encourage using these other products for eyelash growth is prohibited. No further guidance is necessary.

C. *eBay* Factors

1. Irreparable Injury

Allergan seeks to enjoin its direct competitors, (*see* Athena UCL Order, at 16; Cosmetic Alchemy UCL Order, at 12), a fact that alone may serve as a sufficient basis for granting a permanent injunction. *See, e.g., Fresenius Med. Care Holdings, Inc. v. Baxter Int'l, Inc.*, No. C 03-1431 SBA, 2008 U.S. Dist. LEXIS 79689, 2008 WL 928406, at *3 (N.D. Cal. Apr. 4, 2008), *aff'd in part and rev'd in part, Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 582 F.3d 1288 (Fed. Cir. 2009) (in patent context, noting that "[c]ourts routinely find irreparable harm, and therefore grant permanent injunctions where, as here, the infringer and the patentee are direct competitors"). In fact, one of the reasons the competition is not more pronounced may be because Allergan cannot market its products as cosmetics and sell directly to consumers, unlike Defendants who have skirted FDA and California regulations.

Allergan also argues that it stands to lose, and has already lost, market share to Defendants. Defendants admit that they still sell the products, although the parties dispute whether sales continue in California. If Defendants are allowed to continue selling, it may encourage others to do the same. These facts also support a finding of irreparable injury. *See Celsis in Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012) (finding that price erosion, loss of good will, and loss of business opportunities are adequate grounds for finding irreparable harm); *Cellco P'ship v. Hope*, 469 F. App'x 575, 577 (9th Cir. 2012)

("[E]vidence of threatened loss of prospective customers or goodwill certainly supports the finding of the possibility of irreparable harm."); *Commw. Scientific & Indus. Research Org. v. Buffalo Tech., Inc.*, 492 F. Supp. 2d 600, 603 (E.D. Tex. 2007) (issuing injunction based partly on assertion that if patentee "cannot obtain injunctive relief against [infringer], others will be encouraged to infringe the [patent]"). Therefore, the irreparable injury factor favors a permanent injunction.

2. Inadequacy of Legal Remedies

Allergan contends that legal remedies cannot adequately compensate for its injury. The Court previously held that Allergan is not entitled to restitution, so only injunctive relief is available under the UCL. (*See* Pleadings Order, at 12-13.) Marketing changes alone will not sufficiently remedy the UCL violation. Athena's argument that the damages and injunctive relief Allergan seeks through its patent and false advertising claims would sufficiently compensate Allergan for the UCL misconduct also is unavailing. (*See* Athena PI Opp., at 18.) The requested injunction is narrowly tailored to the UCL claim and will be lifted upon regulatory approval of the products as drugs. The relief Allergan seeks through the patent and false advertising claims is tailored to those causes of action, and any damages Allergan may recover will not be prospective or compensate for unfair competition. Therefore, this factor favors a permanent injunction.

3. Balance of Hardships

Allergan asserts that the balance of hardships heavily favors a permanent injunction because (1) it invested considerable resources in developing Latisse and obtaining regulatory approval from the FDA, unlike Defendants who have exploited the market without such approval; (2) it invested considerable resources in marketing and developing awareness of Latisse among physicians and consumers, which Defendants have taken advantage of; and (3) the injunction would not be a hardship to Defendants because it only requires compliance with the law. (PI Motion, at 13-14.)

The Court has a duty "to balance the interests of all parties and weigh the damage to each." *Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1138 (9th Cir. 2009). Not granting an injunction would allow Defendants to continue to cause irreparable harm to Allergan due to lost sales, loss of a competitive advantage, and lost goodwill. The Court does not take lightly the fact that granting Allergan's requested relief ostensibly would prohibit Defendants from conducting their business nationwide, or that Defendants have attempted to modify their marketing. (Athena PI Opp., at 19-20.) But Defendants have not shown that their activities would be legal in any state or that changing their marketing practices alone will minimize any harm. Further, "being required to comply with the law is not a harm" in itself. *Belks Media v. OnlineNIC*, No. C09-00198 HRL, 2010 U.S. Dist. LEXIS 143946, 2010 WL 7786122, at *4 (N.D. Cal. Aug. 23, 2010) (citing *Triad Sys. Corp. v. Se. Exp. Co.*, 64 F.3d 1330, 1338 (9th Cir. 1995), *superseded by statute on other grounds as recognized in Apple, Inc. v. Psystar Corp.*, 658 F.3d 1150 (9th Cir. 2011)).

Neither defendant can "complain of the harm that will befall it when properly forced to desist from its [unfair competition]," even if the effect is "devastating." *Triad*, 64 F.3d at 1338 (citations omitted). Defendants have had ample time not only to change their marketing practices but also to consider filing for regulatory approval. *See Smith & Nephew, Inc. v. Synthes (U.S.A.)*, 466 F. Supp. 2d 978, 984 (W.D. Tenn. 2006) ("'Only hardships to the defendant [that] is not an inseparable part of the plaintiff's right is cognizable." (quoting *Canadian Lumber Trade Alliance v. United States*, 441 F. Supp. 2d 1259, 1267, 30 Ct. Int'l Trade 892 (Ct. Int'l Trade 2006))); *Fresenius*, 2008 U.S. Dist. LEXIS 79689, 2008 WL 928496, at *5 ("Although it has had over a year to take commercially reasonable steps to redesign its machine, [infringer] has apparently taken no action to ease any hardship it may suffer as a result of an injunction."). Cosmetic Alchemy's other argument--that it should be given the opportunity to change its marketing--is unavailing for the reasons discussed above. Therefore, the balance of hardships favors an injunction.

4. Public Interest

Allergan also contends that the public interest would be served by an injunction because it would ensure that Defendants' drugs are tested for efficacy and safety prior to continued sale. (PI Motion, at 14.) The Court agrees. The counterarguments--regulatory bodies should determine if an injunction serves the public interest and an injunction would decrease competition--are unpersuasive. Regulations require over-the-counter

hair growth products must be demonstrably safe and effective for such use prior to marketing, but Defendants' products have not been tested or approved. *Kasz*, 855 F. Supp. at 541 (citing 21 C.F.R. § 310.527; 21 U.S.C. § 355). "[A] court must effectively safeguard the public interest against the abuses inflicted by a willful, persistent violation of regulatory legislation who has not shown good faith in compliance." *United States v. Lit Drug Co.*, 333 F. Supp. 990, 999 (D.N.J. 1971) (citing *May Dep't Stores Co. v. N.L.R.B.*, 326 U.S. 376, 391, 66 S. Ct. 203, 90 L. Ed. 145 (1945)). Thus, although a court may "deny a motion for injunctive relief where the injunction would hinder, rather [than] promote, competition in the market," *Theme Promotions, Inc. v. News Am. Mktg. FSI*, 546 F.3d 991, 1009 (9th Cir. 2008), an injunction is appropriate here because it would protect consumers and Allergan by promoting *fair* competition and compliance with the law by ensuring that Defendants cannot market and sell a misbranded, untested drug. This interest is not diminished due to Allergan's desire for profits.

Accordingly, all four *eBay* factors generally favor a permanent injunction.

IV. CONCLUSION

For the foregoing reasons, the Court **GRANTS** Allergan's Motion for Permanent Injunctions. Based on the recommendations and statements from the parties at oral argument, the Court imposes the following injunctions:

(1) Defendant Athena Cosmetics, Inc., its officers, agents, servants, employees, and attorneys or those in active concert or participation with them who have actual notice of the injunction (collectively "Enjoined Athena Parties") shall cease and forbear from manufacturing, causing to be manufactured, marketing, selling, and/or offering for sale anywhere within the United States any and all eyelash growth product(s). This includes (1) RevitaLash, RevitaLash Enhanced, and RevitaLash Advanced; (2) any product that includes any prostaglandin, including derivatives or analogs thereof, that is marketed, promoted or otherwise directed for application directly or adjacent to the eyelid or eyelash; and/or (3) any other product marketed, promoted or otherwise directed for eyelash growth (collectively, "Enjoined Athena Products"). The Enjoined Athena Parties are further enjoined from stating that their other products are the same as, similar to, more effective than, or intended for the same uses as RevitaLash, RevitaLash Enhanced, RevitaLash Advanced, or Latisse. Notwithstanding any other provision of this Permanent Injunction, the Enjoined Athena Parties may manufacture, cause to be manufactured, market, sell, or offer for sale Enjoined Athena Products where the object of such activities is the consummation of a sale outside the United States, whether such activities are conducted within or outside the United States. For purposes of this exclusion, "sale" includes provision of an Enjoined Athena Product for promotional, research or like purposes, whether or not an Enjoined Athena Party is compensated for the transaction.

(2) Defendant Cosmetic Alchemy, LLC, its officers, agents, servants, employees, and attorneys or those in active concert or participation with them who have actual notice of the injunction (collectively, "Enjoined Cosmetic Alchemy Parties") shall cease and forbear from manufacturing, causing to be manufactured, marketing, selling, and/or offering for sale anywhere within the United States any and all eyelash growth product(s). This includes (1) LiLash; (2) any product that includes any prostaglandin, including derivatives or analogs thereof, that is marketed, promoted or otherwise directed for application directly or adjacent to the eyelid or eyelash; and/or (3) any other product marketed, promoted or otherwise directed for eyelash growth (collectively, "Enjoined Cosmetic Alchemy Products"). The Enjoined Cosmetic Alchemy Parties are further enjoined from stating that their other products are the same as, similar to, more effective than, or intended for the same uses as LiLash or Latisse. Notwithstanding any other provision of this Permanent Injunction, the Enjoined Cosmetic Alchemy Parties may manufacture, cause to be manufactured, market, sell, or offer for sale Enjoined Cosmetic Alchemy Products where the object of such activities is the consummation of a sale outside the United States, whether such activities are conducted within or outside the United States. For purposes of this exclusion, "sale" includes provision of an Enjoined Cosmetic Alchemy Product for promotional, research or like purposes, whether or not an Enjoined Cosmetic Alchemy Party is compensated for the transaction.

Should either party seek a certification of this Order pursuant to Fed. R. Civ. P. 54(b), an appropriate application shall be presented.

IT IS SO ORDERED.

APPENDIX C — OPINION OF THE UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA, FILED OCTOBER 11, 2012

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

SACV 07-1316 JVS (RNBx) consolidated with SACV 08-427 JVS (RNBx) and SACV 09-328 JVS (RNBx)

Allergan, Inc., *et al.*

v.

Athena Cosmetics, Inc., *et al.*

October 11, 2012, Decided
October 11, 2012, Filed

Present: The Honorable James V. Selna

Nancy Boehme	Not Present
Deputy Clerk	Court Reporter

Attorneys Present for Plaintiffs: Not Present.

Attorneys Present for Defendants: Not Present.

OPINION

Proceedings: (In Chambers) Order re Motions for Reconsideration, to Dismiss, and To Strike

Appendix C

Defendant and counter-plaintiff Athena Cosmetics, Inc. ("Athena") moves the Court for reconsideration of its July 19, 2012 order ("SJ Order") pursuant to Federal Rule of Civil Procedure 59(e) or 54(b). (Docket No. 752.) Athena has also moved for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c) on Allergan's fourth, fifth, and sixth claims for relief. (Docket No. 751.) Plaintiff and counter-defendant Allergan Inc. ("Allergan") moves pursuant to Federal Rule of Evidence 702 and 402 and Federal Rule of Civil Procedure 37 to strike the Sheldon Bradshaw and Patrick Noonan declarations submitted in support of Athena's motions. (Docket No. 755.) The motions are opposed. For the following reasons the motions are DENIED.

I. BACKGROUND

Allergan's fourth claim for relief against Athena is for violation of the California Business and Professions Code § 17200 *et seq.* ("UCL"). (Consolidated Amended Complaint ("CAC") ¶¶ 73-85, Docket No. 576.) The fifth is a Lanham Act false advertising claim and the sixth a state false advertising claim. (*Id.* at ¶¶ 86-94.)

On March 16, 2012, Allergan moved for partial summary judgment on its fourth claim for relief as against Athena. (Docket No. 628.) On March 23, 2012, Athena and other defendants moved for judgment on the pleadings on Allergan's fourth, fifth, and sixth claims. (Docket No. 639.) After a hearing on May 14, 2012, the Court denied the motion for judgment on the pleadings on May 16, 2012.

(Judgment on the Pleadings Order ("JOP Order"), Docket No. 685.) After another hearing on July 16, 2012, the Court granted Allergan's motion for partial summary judgment on July 19, 2012. (SJ Order 1, Docket No. 711.)

On August 16, 2012, Athena filed its present motions and on August 30, 2012, Allergan filed its motion to strike.

II. LEGAL STANDARD

Rule 54(b) provides that "any order or other decision, however designated, that adjudicates fewer than all the claims or the rights and liabilities of fewer than all the parties does not end the action as to any of the claims or parties and may be revised at any time before the entry of a judgment adjudicating all the claims and all the parties' rights and liabilities." Fed. R. Civ. P. 54(b). In this district, Local Rule 7-18 governs motions for reconsideration:

> A motion for reconsideration of the decision on any motion may be made only on the grounds of (a) a material difference in fact or law from that presented to the Court before such decision that in the exercise of reasonable diligence could not have been known to the party moving for reconsideration at the time of such decision, or (b) the emergence of new material facts or a change of law occurring after the time of such decision, or (c) a manifest showing of a failure to consider material facts presented to the Court before such decision. *No motion for*

> *reconsideration shall in any manner repeat any oral or written argument made in support of or in opposition to the original motion.*[1]

L.R. 7-18 (emphasis added). The Court has discretion in determining whether to grant a motion for reconsideration. *See Navajo Nation v. Confederated Tribes & Bands of the Yakama Indian Nation*, 331 F.3d 1041, 1046 (9th Cir. 2003) ("Whether or not to grant reconsideration is committed to the sound discretion of the court.").[2]

III. DISCUSSION

A. Motion for Judgment on the Pleadings

As a preliminary matter, the Court notes that it considers the motion for judgment on the pleadings based on preemption as a motion for reconsideration and treats it as such. The motion seeks judgment on the fourth, fifth, and sixth claim for relief as preempted. One claim, the fourth, the Court has already granted judgment to Allergan. The two others the Court has

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1. *See also School Dist. No. 1J, Multnomah Cnty. v. ACandS, Inc.*, 5 F.3d 1255, 1263 (9th Cir. 1993) (providing that reconsideration is appropriate if the movant demonstrates clear error, manifest injustice, newly discovered evidence, or an intervening change in controlling law).

2. Athena also moves pursuant to Rule 59(e), arguing the Court's order is an effective injunction. (Reconsideration Mot. Br. 3-4, Docket No. 752.) However, it represents the standard is the same as Rule 54 for purposes of its motion. (*Id.* at 5.)

previously denied judgment on the pleadings. (JOP Order 1.) The motion seeks to vacate portions of the Court's SJ order. (12(c) Mot. Br. 12, Docket No. 751.) The argument here shadows or is identical to those made in both the previous 12(c) motion and in opposition to the summary judgment motion; namely, that the Court should defer to agency determination and not adjudicate the claim. The difference is one of degree. Therefore, the motion is properly considered a motion for reconsideration of the Court's SJ and JOP orders.

The Court denies the motion because it fails to present any ground warranting reconsideration. Every argument made is either one that was previously made or could have been made. L.R. 7-18 (barring repetition of previously made arguments); *Kona Enters., Inc. v. Estate of Bishop*, 229 F.3d 877, 890 (9th Cir. 2000) (holding reconsideration motions "may not be used to raise arguments or present evidence for the first time when they could reasonably have been raised earlier in the litigation). Preemption was pled as an affirmative defense and no materials presented in the motions were not previously unavailable during the pendency of these motions. (Affirmative Defenses, ¶¶ 16, 18, Docket No. 583.) Additionally, the preemption argument does not demonstrate clear error; no court has found a UCL claim based on California Health and Safety Code is preempted, nor created a distinction between interpretation and application. *See In re Farm Raised Salmon*, 42 Cal.4th 1077, 1099, 72 Cal. Rptr. 3d 112, 175 P.3d 1170 (2008), *cert. denied*, 555 U.S. 1097, 129 S. Ct. 896, 173 L. Ed. 2d 106.

B. Motion for Reconsideration

The Court also finds that the motion for reconsideration of the Court's SJ order fails to present any grounds warranting reconsideration. All arguments contained therein "repeat [] oral or written argument made in support of or in opposition to the original motion." L.R. 7-18. To the extent any argument was not made in opposition to the motion, Athena has not presented grounds for why it could not have been earlier presented. They are thus waived. *Novato Fire Protection Dist. v. United States*, 181 F.3d 1135, 1141 n.6 (9th Cir. 1999). Finally, the Court finds no showing of clear error for the reasons stated in the SJ order.

The Court notes that the mentions of the FDCA throughout the order are referential. In order to properly adjudicate Allergan's UCL claim, the Court must examine whether the Sherman Act is violated. In order to determine if the Sherman Act is violated, the Court looks to whether the federal regulations incorporated therein are violated. This is what the Court did, nothing more.

C. Motion to Strike

In light of the above, the Court finds the motion to strike the supporting declarations moot but notes they do appear to be primarily legal argument. Nevertheless, the motion will be denied as moot.

V. CONCLUSION

For the foregoing reasons. The motions are denied.

IT IS SO ORDERED.

APPENDIX D — OPINION OF THE UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA, FILED JULY 19, 2012

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. SACV 07-1316 JVS (RNBx)
consolidated with
SACV 08-427 JVS (RNBx) and SACV 09-328 JVS (RNBx)

Title *Allergan, Inc., et al. v. Athena Cosmetics, Inc. et al.*

Date July 19, 2012

Present: The Honorable James V. Selna

Karla J. Tunis	Not Present
Deputy Clerk	Court Reporter

Attorneys Present for Plaintiffs: Not Present

Attorneys Present for Defendants: Not Present

Proceedings: **(IN CHAMBERS)**
Order GRANTING Plaintiffs' Motion for Partial Summary Judgment Against Defendant Athena Cosmetics, Inc. On Allergan's Fourth Claim for Relief (Fld 3-19-12, #628 & 630)

Appendix D

The present action involves several claims and counter-claims regarding eyelash and hair products. Plaintiff and counter-defendant Allergan, Inc. ("Allergan") moves the Court for partial summary judgment on its fourth claim for relief against Athena Cosmetics, Inc. ("Athena") pursuant to Federal Rule of Civil Procedure 56. Athena opposes the motion. For the following reasons, the motion is GRANTED.

I. BACKGROUND

Allergan's fourth claim for relief is a cause of action asserted against all defendants in the case for violation of California Business and Professions Code §§ 17200 *et seq* (the "UCL"). (First Amended Complaint ("FAC") ¶¶ 73-85, Docket No. 576.) It alleges that the defendants unlawfully marketed, sold, and distributed hair and eyelash growth products. (*Id.* at 74.)

Allergan now argues that uncontroverted facts establish this claim against Athena. (Mot. Br. 1, Docket No. 628.) It argues that under the governing statutory scheme, it is clear that Athena's RevitaLash line of products are new drugs sold without proper approval and misbranded in violation of California law as well as the federal statutes which California law incorporates. (*Id.*) Because these actions are business actions, Allergan asserts, Athena is in violation of the UCL. (*Id.*)

Athena contends that the evidence does not and cannot establish that its products are drugs under the relevant statutes. (Opp'n Br. 1, Docket No. 649.) Additionally, it

argues that certain administrative agency actions show that these agencies have concluded the products are not drugs and the Court should follow those findings. (*Id.*) Athena also makes several arguments in opposition that it made and the Court considered in relation to its motion for judgment on the pleadings. (*Id.*; Judgment on the Pleadings Order II ("JOP II Order"), Docket No. 685.)

II. LEGAL STANDARD

Summary judgment is appropriate only where the record, read in the light most favorable to the nonmoving party, indicates that "there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986). Summary adjudication, or partial summary judgment "upon all or any part of a claim," is appropriate where there is no genuine issue of material fact as to that portion of the claim. Fed. R. Civ. P. 56(a), (b); *see also Lies v. Farrell Lines, Inc.*, 641 F.2d 765, 769 n.3 (9th Cir. 1981) ("Rule 56 authorizes a summary adjudication that will often fall short of a final determination, even of a single claim . . . .") (internal quotation marks omitted).

Material facts are those necessary to the proof or defense of a claim, and are determined by reference to substantive law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). "[A] complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." *Celotex*, 477 U.S. at 322. A fact issue is genuine "if the evidence is such that a

reasonable jury could return a verdict for the nonmoving party." *Anderson*, 477 U.S. at 248. To demonstrate a genuine issue, the opposing party "must do more than simply show that there is some metaphysical doubt as to the material facts. . . . [T]he nonmoving party must come forward with specific facts showing that there is a genuine issue for trial." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986) (internal quotation marks and citations omitted). In deciding a motion for summary judgment, "[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." *Id.* at 255. Nevertheless, inferences are not drawn out of the air, and it is the opposing party's obligation to produce a factual predicate from which the inference may be drawn. *See Richards v. Nielsen Freight Lines*, 602 F. Supp. 1224, 1244-45 (E.D. Cal. 1985), *aff'd*, 810 F.2d 898, 902 (9th Cir. 1987).

The burden initially is on the moving party to demonstrate an absence of a genuine issue of material fact. *Celotex*, 477 U.S. at 323.[1] If the moving party meets its burden, then the nonmoving party must produce enough evidence to rebut the moving party's claim and create a genuine issue of material fact. *See id.* at 322-23. If the nonmoving party meets this burden, then the motion will

1. At oral argument, Athena raised as an issue the burden of proof. It attempted to tie this burden to deference to agency determinations (in this case purported implicit determinations through inaction). The Court addressed deference to inaction in its JOP II order. As discussed below, the Court finds that Allergan has met its *Celotex* burden for its claim and finds no other basis for a different burden of proof to be applied here.

be denied. *Nissan Fire & Marine Ins. Co. v. Fritz Co., Inc.*, 210 F.3d 1099, 1103 (9th Cir. 2000).

III. UNCONTROVERTED FACTS

The parties have presented evidence, purportedly uncontroverted facts supported by that evidence, alleged factual disputes presented by the evidence, and objections to that evidence. To the extent any disputed facts or objections are material to the Court's decision, the disputes are resolved as stated herein. Disputes over evidence the Court does not rely on are immaterial, and the Court does not rule on them. The facts discussed herein are uncontroverted, except as may be noted below.

A. Entities

Allergan is a pharmaceutical company that manufactures the Federal Drug Administration ("FDA") approved drugs Latisse® and Lumigan®. (Statement of Uncontroverted Facts ("SUF") ¶¶ 1, 2, 4, 7, Docket No. 628-1.)[2] Both contain Bimatoprost, a prostaglandin analog. (*Id.*

2. Athena expressly acknowledges many facts proffered by Allergan are uncontroverted. (*See* Statement of Genuine Issues ("SGI"), Docket No. 649-1.) As to these facts, the Court cites to Allergan's SUF by paragraph number. More detailed citations to the record are found therein. Additionally, per Local Rule 56-3, "the Court may assume that the material facts as claimed and adequately supported by the moving party are admitted to exist without controversy except to the extent that such material facts are (a) included in the 'Statement of Genuine Disputes' and (b) controverted by declaration or other written evidence filed in opposition to the motion."

at ¶¶ 2-4.) Lumigan is used to treat Glaucoma and Latisse is approved to promote eyelash growth. (*Id.* at ¶¶ 4, 6.)

Athena represents itself as a cosmetics company. It manufactures several products whose precise classification is the subject of this dispute. (*Id.* at ¶ 10.) It has manufactured and manufactures several products under variations of the name RevitaLash®, RevitaBrow®, and Hair by RevitaLash®. (*Id.*; Athena's Additional Undisputed Facts ("AUF") ¶ 1, Docket No. 649-1.)[3]

Athena was founded by Dr. Michael Brinkenhoff ("Dr. Brinkenhoff"), an ophthalmologist who currently serves as Athena's president and CEO. (SUF ¶ 9.) It commenced producing and selling RevitaLash essentially at the same time it was incorporated, November 2005. (Carter Decl. Ex. 1 ("Brinkenhoff Dep.") 13:21-14:5, Docket No. 633-1.) Through his ophthalmology practice, Dr. Brinkenhoff became aware that glaucoma drugs containing prostaglandin analogs had a high level of safety and caused "eyelashes to grow thick and long." (SUF ¶ 13; Brinkenhoff Dep. 48:11-19.)[4] He began directing patients with uneven eyelash growth to use these drugs on the eyelid that lacked growth as an off-label use of the drug to grow the eyelashes. (SUF ¶ 13.) He then treated his

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3. Allergan also expressly does not dispute several facts that Athena provides. (*See* Reply to SGI, Docket No. 664-1.) The Court cites to these by Athena's AUF paragraph number.

4. Athena purports to dispute this fact but it does not actually controvert it and only provides non-conflicting supplementary facts in its SGI. (*See* SGI ¶ 13.) The fact is therefore uncontroverted.

wife's eyelashes with one of these drugs in order for them to grow after she had undergone chemotherapy. (*Id.* at ¶14.)[5] These experiences gave Dr. Brinkenhoff the idea of creating RevitaLash as a product to promote the growth of eyelashes. (*Id.* at ¶¶ 13, 14.)

B. Marketing and Sales Structure

Athena has produced, marketed, and sold several compounds that are called at least in part RevitaLash. (*Id.* at ¶ 10.) Generally, only one compound under one name was sold at a time and a different name was created for each new formulation, though still incorporating RevitaLash. The marketing of these products has also modified but not necessarily correlated with specific changes to varietal name and formulation. Athena has used and continues to use the website "www.revitalash.com" to market and sell its RevitaLash compounds. (*Id.* at ¶ 17.)[6] The website contains pricing information, testimonials from customers, frequently asked questions ("FAQ"), the

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5. Athena purports to dispute this fact but it does not actually controvert it and only provides non-conflicting supplementary facts in its SGI. (*See* SGI ¶ 14.) The fact is therefore uncontroverted.

6. Athena disputes this fact because Allergan's phrasing does not delineate the different iterations of RevitaLash and that only one formulation is currently available on the site. (SGI ¶ 17.) Based on the evidence provided by both parties, the fact as stated by the Court is uncontroverted. (*See e.g.*, Carter Decl. Ex. 5 p. 94 ("Defendant further admits information concerning [previous iterations of RevitaLash] have been made available at http://www.revitalash.com at the time such products have been offered for sale.").)

story of RevitaLash's development, media stories about RevitaLash products, and other promotional statements. (*Id.* at ¶¶ 17, 18, 38; Carter Decl. Exs. 24, 34, 37-40.)

Athena also conducts marketing via official Facebook pages for RevitaLash and Athena Cosmetics. (SUF ¶ 19.)[7] It also promotes and has promoted its products through press releases, magazine articles, testimonials, and in direct communication with resellers and consumers. (*Id.* at ¶ 20.)[8] Athena uses more than 11,000 resellers to help promote, advertise, and sell its RevitaLash products. (*Id.* at ¶ 29.)[9] Athena also maintains a program for "Authorized" resellers where they display a certain logo and agree to limitations on how they market advertise and sell RevitaLash. (SGI ¶ 31.) Prior to granting authorized reseller statues, Athena's president must review and give written approval of the website and marketing proposals for RevitaLash products. (SUF ¶ 32.) The messages being communicated by these different channels of promotion,

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7. Athena purports to dispute this fact but it does not actually controvert it and only provides non-conflicting supplementary facts in its SGI. (*See* SGI ¶ 19.) The fact is therefore uncontroverted.

8. Athena purports to dispute this fact but it does not actually controvert it and only provides a non-conflicting narrower statement of this fact in its SGI. (*See* SGI ¶ 19.) It appears to take issue with the present tense statement of the fact combined with the broad term RevitaLash. (*Id.*) The Court therefore restates the fact slightly modified and finds it is uncontroverted as stated.

9. Athena contends that not all of these resellers have been established as authorized resellers. (SGI ¶ 29.) However, the fact does not state these resellers are authorized. The fact is thus uncontroverted.

sales, and advertising have changed over time. The Court first lays out the uncontroverted facts about the past formulations and marketing that have been subsequently changed. It then proceeds to the best evidence of the current state of marketing and the new formulation.

C. Previous Formulations and Marketing

1. Formulations, Naming, and Labeling

The first eyelash product Athena produced was termed RevitaLashMD. (Carter Decl. Ex. 2 Resp. 4, Docket No. 633-2.) It was sold from November 2006 to June 2007, contained Bimatoprost, and was sold over the counter. (*Id.*) Dr. Brinkenhoff told his compound supplier that he intended to sell RevitaLashMD as a eyelash growth product. (SUF ¶ 16.) The ingredient labeling of RevitaLashMD® originally listed Bimatoprost as "Formula LashGro." (Carter Decl. Ex. 4 p. 1.) The box and labeling of the product included the statements "Physician Formulated" and "Longer, Thicker, Fuller Lashes In 60 Days Guaranteed." (*Id.* at p. 3.)

Starting in January 2007, the California Department of Health Services commenced an investigation of RevitaLash. (*Id.* Ex. 52.) It interacted with Athena personnel in the following months and sent a "Regulatory Letter" to Athena on April 27, 2007. Subsequent to the investigation being commenced, in March and April 2007, Athena kept the same formulation for its product but changed the name to "RevitaLash®" and changed the ingredient list to indicate Bimatoprost instead of "Formula LashGro." (*Id.*) It also began to include an insert with the

product that stated that it was not intended to treat hair loss or to promote the growth of hair. (*Id.* at Ex. 4, p. 1.) However, in May through July 2007, Athena commissioned an efficacy study on its RevitaLash product whose objective included evaluating the effectiveness "on eye lash length and fullness and to determine the lowest level of active ingredient in the test product that works in the product matrix." (*Id.* at Ex. 78, p. 3.)

In November, 2007, Athena changed the formula of "RevitaLash," replacing Bimatoprost with triflouromethyl dechloro ethylprostenolamide ("TDE"), a prostaglandin analog. (*Id.* at Ex. 2.) It maintained the same name for the product. (*Id.*) Athena made the change in response to the Federal Drug Administration's ("FDA") seizure of another company's bimatoprost containing eyelash growth product. (SUF ¶ 45.)[10] Dr. Brinkenhoff and Athena believed that TDE caused eyelash growth and that this version of RevitaLash would thus continue to cause eyelash growth. (SUF ¶ 46.) This product was sold until in or around January, 2011. (Athena's Answer to Amended Complaint ¶ 45, Docket No. 583.) This suit was filed on November 7, 2007. (Docket No. 1.)

On January 12, 2010, the Court issued its first claim construction order in this case. (Docket No. 463.) In September 2010, Athena started producing "RevitaLash Enhanced®" which no longer contained TDE but instead

10. Athena purports to dispute this fact "to the extent Allergan mis-characterizes Dr. Brinkenhoff's testimony." (SGI ¶ 45.) It provides nothing further explaining this statement. (*Id.*) The Court finds this fact is therefore uncontroverted.

Isopropyl cloprostenate, another prostaglandin analog. (Carter Decl. Ex. 2; SUF ¶ 47.)

2. Marketing

Because the marketing message has been modified over time, it is unclear when certain messages were modified. However, at some point through this time the following statements and promotions were made. Athena promoted its RevitaLash formula available at the time by listing "the story" of the products development. This story states that Dr. Brinkenhoff made the product for his wife's eyelashes after she received cancer treatment and that it allowed her to recover her eyelashes. (Carter Decl. Ex. 52 p. 30.) Several testimonials included on Athena's RevitaLash website discussed the person's eyelash "growth." (*Id.* at p. 231.) Certain resellers and sales representatives sent emails asking about how eyelashes were growing, discussing ways to market the product over other eyelash growth products and even Latisse in particular, and received emails for promotional material discussing eyelash length. (SUF ¶ 28; Carter Decl. Exs. 17, 42-47; Nguyen Decl. ¶ 6.) Several articles in magazines and other areas discussed RevitaLash products, "the story," and resulting eyelash growth from use. (SUF ¶ 22; Carter Decl. Ex. 18-20, 22.) The Facebook pages included several pictures depicting growth.(Carter Decl. Exs. 7-11.) Generally, Athena emphasized in its marketing the ability of RevitaLash products to grow eyelashes. (SUF ¶ 21.)[11]

11. Athena disputes this fact only as to the current formulation; thus the fact is uncontroverted. (SGI ¶ 21.)

D. Current Formulation and Marketing

In or around June 2011, Athena switched its current RevitaLash offering to "RevitaLash Advanced®" with dechloro dihyroxy difluoro ethylcloprotenomaide ("3D") as its active ingredient. (SUF ¶ 49.) 3D is also a prostaglandin analog. (*Id.*) A three month supply of the product is sold on the RevitaLash website for $98.00 while a 6 month supply is sold for $150.00. (Carter Decl. Ex. 6.) The labeling and promotions state that the product is an "eyelash conditioner" and helps your eyelashes "appearance." (*Id.* at Ex. 37.) The instructions for application dictate that one preferably place the product on one's eyelashes at night once and that over several weeks a difference in "appearance" will be noted. (*Id.* at Exs. 63, 68.)

The RevitaLash website and most resellers now also contain only references to modifying the "appearance" of eyelashes. (*Id.* at Exs. 34, 40.) Just as "the story" states it was developed to restore the look of Dr. Brinkenhoff's wife's eyelashes. (*Id.* at Ex. 39.) Nevertheless, different promotions continue to reference Latisse or prescription alternatives. (*Id.* at 36.) Certain resellers, not necessarily authorized, continue to reference eyelash growth. (*Id.* at Exs. 58, 59.)

IV. DISCUSSION

The Court first details the relevant statutory framework underlying Allergan's claim to determine the relevant question at issue. Next the Court analyzes whether Athena's RevitaLash products were and are

drugs as defined by that framework. After examining all the evidence, the Court determines that the RevitaLash products are drugs beyond any genuine issue of material fact. Based on this conclusion, the Court finds that Allergan is entitled to judgment on its fourth claim for relief, violation of the UCL.

A. Statutory Scheme

"The UCL's purpose is to protect both consumers and competitors by promoting fair competition in commercial markets for goods and services." *Kasky v. Nike, Inc.*, 27 Cal.4th 939, 949 (2002). The scope is of the act is broad. *Id.* It prohibits "any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising and any act prohibited by [California's False Advertising Law]." Cal. Bus. & Prof. Code § 17200. In order to bring an action under the UCL, a private party must have "suffered injury in fact and ha[ve] lost money or property as a result of the unfair competition." *Id.* at § 17204. A claim under the UCL against a party for an unlawful business practice can be based on any act or practice committed pursuant to business activity that is at the same time forbidden by law, whether federal, state, or local. *Hale v. Sharp Healthcare*, 183 Cal. App. 4th 1373, 1382-83 (2010).

This includes UCL claims based on violations of California's Health and Safety Code. *In re Farm Raised Salmon Cases*, 42 Cal.4th 1077, 1095-96 (2008). The fact that California Health and Safety Code provisions may be identical to FDCA provisions or that claims refer to FDA

regulations does not change the ability for these violations to be a proper basis for a UCL claim. *Id.* at 1096; *Delacruz v. Cytosport, Inc.*, 2012 U.S. Dist. LEXIS 90847 at * 19 (N.D. Cal. June 28, 2012).

Allergan's fourth cause of action alleges that Athena engages in unlawful business practice and acts. (Mot. Br. 1, 2.) It contends that several of Athena's activities made pursuant to its business violate the California Health and Safety Code and federal provisions governing the sale of new and misbranded drugs. (Mot. Br. 1, 2.) These specific provisions prohibit the sale of misbranded products and "new drugs" absent preapproval. 21 U.S.C. § 355(a); Cal. Health and Safety Code §§ 111550, 110398, 111440. Under 21 C.F.R. § 310.527(b), incorporated into California law by Cal. Health and Safety Code § 110110, any over the counter ("OTC") drug purportedly for growing hair is a "new drug" per se for purposes of the Federal Food, Drug, and Cosmetic Act ("FDCA") and thus for Cal. Health and Safety Code § 111550. Further, any product considered a new drug that is sold without an approved new drug application is misbranded for purposes of Cal Health and Safety Code §§ 110398, 111440.

The Court previously resolved Allergan's standing to bring this UCL action and whether the action should be stayed or dismissed under the primary jurisdiction doctrine.[12] (JOP II Order 3-11.) It was determined that

12. Athena submitted a Notice of Supplemental Materials Related to Pending Motions Concerning Allergan's Fourth Claim for Relief to which Allergan filed a reply. (Docket Nos. 696, 698.) All of Athena's material appears aimed at the question of whether

Allergan sufficiently pled an injury in fact by alleging it lost sales, revenue and market share. *Allergan, Inc. v. Athena Cosmetics, Inc.*, 640 F.3d 1377, 1382-83 (Fed. Cir. 2011). The Court now must determine whether the uncontroverted facts show Athena's RevitaLash products are drugs for purposes of the FDCA and the California Health and Safety Code.

B. Is RevitaLash a Drug?

Under these statutes, substances are drugs if they are "(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321 (g)(1); Cal. Health and Safety Code § 11014. "The drug definition is to be given a liberal interpretation in light of the remedial purposes of the legislation." *National Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325, 336 (2d Cir. 1977) (citing *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 792, 798 (1968). The terms "drug" and "cosmetic" are not necessarily mutually exclusive; a product may be both a cosmetic and a drug if it falls within the statutory definition of both. *United States. v. Article Consisting of 36 Boxes, More or Less, Labeled "Line Away, Temporary*

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the Court should endeavor to consider the issue presented by Allergan's motion or defer in some way to agency action. (*Id.*) The Court has already ruled on this matter when denying the motion for judgment on the pleadings. (*See* JOP II Order 12.) Additionally, the Court has reviewed the provided authority and materials and finds they do not present grounds for disturbing that decision.

Wrinkle Smoother, Coty", 284 F.Supp. 107, 110 (D.C. Del. 1968) *aff'd*, 415 F.2d 369 (3rd Cir. 1969).

Allergan argues that the uncontroverted facts establish that the RevitaLash products are drugs under section (C) as a matter of law because they are intended to affect a function of the body–eyelash growth. (Mot. Br. 1-2.)

Athena argues that its current RevitaLash product is marketed and sold in such a way that it cannot be established beyond a genuine issue of material fact that it is objectively intended to affect a function of the body. (Opp'n Br. 1.) It believes the evidence establishes that RevitaLash Advanced is a cosmetic only intended to beautify and improve one's appearance. (*Id.* at 2.) Further, it argues that much of the evidence Allergan marshals in support of its position is improper to consider and irrelevant. (*Id.* at 14.) Finally, it argues that the FDA has implicitly decided that RevitaLash as currently marketed, labeled, and sold is a cosmetic, and therefore is not a drug. (*Id.* at 20-22.)

1. Intended Use Standard

In determining whether a product is intended to affect a bodily function, a vendor's objective intent in promoting, distributing, and selling the product is the key consideration. *United States v. Kasz*, 855 F.Supp 534, 539 (D.R.I. 1994) *accord U.S. v. Storage Spaces Designated Nos. 8 and 49 Located at 277 East Douglas, Visalia Cal.*, 777 F.2d 1363, 1366 (9th Cir. 1985) cert. denied, 479 U.S. 1086 (1987). "[T]he objective intent of the vendor, not

the vendor's subjective explanations and disclaimers" determines the intended use of a product. *Kasz*, 855 F.Supp at 542. This inquiry prevents a party from hiding behind stated disclaimers that a product is "not for drug use" or "no claim is made that the product cures anything" when the overall circumstances indicate a different true intent based on objective evidence. *Id.* at 543.

2. Evidence of Intent

Vendor intent may be derived or inferred from labeling claims, promotional material, advertising material, oral and written statements, evidence that the vendor is aware that his product is being offered or used by others for a purpose for which it is neither labeled nor advertised, or any other relevant source. *Storage Spaces*, 777 F.2d at 1366; *Kasz*, 855 F.Supp. at 539. Athena appears to contend that it is improper to consider statements of subjective intent from a manufacturer to establish the intended use of a product. (Opp'n Br. 16-17.) It relies on the case law's focus and statements about objective evidence and intent. (*Id.*) As Allergan correctly points out, this reliance is misplaced. (Rep. Br. 5-6, Docket No. 665.) The doctrine Athena relies on involves overcoming self-serving statements or disclaimers of subjective intent in view of objective evidence of true intent. *See Kasz* 855 F.Supp at 539. They do not minimize the relevance or weight of statements of a vendor's subjective intent that a product be used to affect the body or a bodily function.

Athena also argues that "the physical properties of a product or the effect of a product on the body is not relevant

to whether a product is a drug under the FDCA." (Opp'n Br. 14.) However, the cited authority does not stand for this proposition; it only states that the determinative question is what the intended use is, not the physical properties. *Kasz*, 855 F.Supp at 539. It does not state that physical properties cannot be relevant to determining intent. *Id.*

Finally, Athena also argues that past labeling, marketing, and promotions "are not relevant to the determination as to whether RevitaLash Advanced® is a drug." (Opp'n Br. 17.) It argues that other cases have only relied on past marketing efforts etc. in structuring appropriate relief. (*Id.*) Allergan provides in reply cases considering past marketing and labeling etc. both for remedies and violations when the current labeling has been relevantly changed. (Rep. Br. 9 (citing *United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d. 547, 569 (D.N.J. 2004);*United States v. Kasz Enterprises, Inc.*, 862 F.Supp. 717, 722 (D.R.I. 1994) (hereinafter *Kasz II*); *Kasz*, 855 F.Supp. 535-38).)

Further, it is unclear why such evidence would be relevant for a remedy for a violation but not for the violation itself. Athena may try to distinguish these cases based on their changes to the formulation and name of its eyelash product over time. Such a distinction is unconvincing. Here all the products begin with the word "RevitaLash," are similarly applied, have been introduced to replace the other, and Athena states the formula changes to make it work better. (*See* Section III. B, *supra* p. 4.) Thus, the reasoning of *Kasz II* rings especially true: "that the consequences of the past promotional activities of the

defendants will linger for an unknown period of time into the future." 862 F.Supp at 722. Here Athena is purposely encouraging that lingering for the new formulas by keeping the same name.

Accordingly, the Court finds no reason to disregard or not consider any of the categories of evidence that Athena points to as irrelevant or otherwise improper. The Court now turns to the uncontroverted evidence to determine if it supports a finding as a matter of law that Athena's RevitaLash products are drugs.

3. Application and Conclusion

Athena focuses its opposition only on whether the evidence can show that the current formulation and iteration of RevitaLash, RevitaLash Advanced, is intended to affect a bodily function. The Court has ruled that Allergan is possibly entitled to an injunction against past conduct because of a probability of recurrence. (JOP II Order 12.) Thus, whether the past activity was in violation of the UCL because the intent shows it was a drug is a relevant question. Based on the uncontroverted facts and the lack of argument against such a finding, the Court thus finds that all previous versions and iterations of RevitaLash were intended to affect a bodily function–hair growth. Thus, the products were drugs within the meaning of the FDCA and the Cal. Health and Safety Code.

Considering all the uncontroverted facts, the Court finds that the objective vendor intent for RevitaLash Advanced is that it be used to affect the growth of eyelashes,

a bodily function. The facts clearly established that the initial iterations of RevitaLash were unambiguously developed and intended to make one's eyelashes longer and fuller. Only changing or adding a second word after the dominant term is not enough to avoid the built up history of intent. The website is www.*revitalash*.com. A choice was made to continue to use "RevitaLash" as part of the name. Various promotional discussions of the product refer to it not as RevitaLash Advanced, but simply as RevitaLash. (*See e.g.*, Carter Decl. Ex. 30, 34, 35, 39.) The different versions replaced one another and were not offered as alternatives, implying they directly replaced the previous version. (*See* Section III. C. 1. *supra* p. 5-6.) Further, the changes to the formulation do not distance RevitaLash Advanced from the previous versions in a significant way where the FAQ and other information indicate that new formulations are intended to work better and improve on the previous versions. (Carter Decl. Ex. 40.) It is evident that prostaglandin or a prostaglandin analogue is the active ingredient in the original RevitaLash formulation and each further formulation as well as in Latisse–and that compound produces hair growth. Thus, it is implied that RevitaLash Advanced is a continuation and improvement on products clearly intended to grow eyelashes. *Kasz II*, 862 F.Supp at 722.

Additionally, several facts about the currently operative marketing, labeling, and promotion taken in isolation from past efforts still show this objective intent. Athena's promoters continue to respond to questions or strategize how to differentiate RevitaLash Advanced from "other options" or Latisse explicitly by pointing only to the

need for a prescription and price, not the function of the product. (Carter Decl. Exs. 30, 36.) Alluding to the need for a prescription is clearly intended to evoke Latisse, a product approved and intended to grow eyelashes. (Section III. A. *supra* p. 3.) Further, in a current marketing presentation slide show for RevitaLash Advanced, it begins by discussing the process and lifecycle for eyelash growth before moving on to discussing the product. (Carter Decl. Ex. 32 ("Eyelash growth is a cyclical process. For example, the lifecycle of eyelash hair is approximately 150-200 days, then it falls out.").) During a "webinar" Athena representatives also spoke to growth occurring naturally or with RevitaLash and that the product tells lashes to "[w]ake up, act like you did when you were younger . . . . [s]tart to become fuller and thicker and longer." (Carter Decl. Ex. 30 p. 156.)[13] This is all considered in light of prevalent claims about making one's lashes "look" or "appear" longer, fuller, and more beautiful; statements championing the replacement of extensions and false eyelashes; and statements about combining use with mascara. One obvious way of making one's lashes look or appear longer while fitting this criteria is to actually make them longer.

The pricing of RevitaLash also points to an intent for it to be a drug, not just a cosmetic. While the disparity may not be as great as that on display in *Kasz*, it still goes to show an intent to be different and considered differently than simple cosmetics. 855 F.Supp. at 543; *Upjohn Co.*

13. Athena points to testimony that this was a misstatement. (SGI ¶ 21.) However, it was stated more than just this instance. (Carter Decl. Ex. 30, p. 152.) Further, even as a misstatement, this shows possible underlying intent or conceptions of the product.

v. Riahom Corp., 641 F.Supp 1209, 1224 (D.Del. 1986). Further, the instructions for application also go to show an objective intent of affecting a bodily function. Athena directs that RevitaLash Advanced be applied preferably at night each day over a period of weeks to see results. Section III. D. *supra* p. 5. This shows an intent that the product doesn't affect immediate appearance but instead changes eyelashes overtime, timing that is related to the lash growth cycle in some marketing.

Finally, the physical formulation of RevitaLash Advanced combined with information disclosed in Athena's recent patent application also provides evidence of an intent to create hair growth. RevitaLash Advanced contains 3D, a formulation disclosed in Athena's U.S. Patent application No. 12/698,823. (SUF ¶ 59; Carter Decl. Ex. 69.)[14] The application is for a "composition, method and kit for enhancing human hair including eyelashes" and states that use of the compounds disclosed will "stimulate or promote the growth of eyelashes" when applied in a manner echoing the instructions for RevitaLash Advanced. (SUF ¶ 60.) The Court finds this is relevant evidence that Athena intends RevitaLash Advanced to stimulate or promote the growth of eyelashes.

The disclaimers made about the product not being a drug or used to cure disease are insufficient to create a genuine issue of fact about vendor intent. *Storage Spaces*,

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14. Athena disputes Allergan's phrasing of this fact because the cited language of the application are not claims. (SGI ¶ 59.) Thus, as the Court states the fact, it is uncontroverted.

777 F.2d at 1366 n.5; *United States v. Undetermined Quantities of Articles of Drug*, 145 F. Supp. 2d 692, 697 (D.Md. 2001). Further, stating that something "is a cosmetic" does not necessarily mean it is not a drug. *Article Consisting of 36 Boxes*, 284 F.Supp. at 110. For the same reasons, Athena's reliance on purported implicit findings by the FDA that its products are cosmetics does not conflict or weigh against finding this intent. (*See* Opp'n Br. 21-22.)

Accordingly, the Court finds that the uncontroverted facts establish as a matter of law that RevitaLash Advanced is objectively intended to grow eyelashes, an effect on a bodily function. Therefore, the Court finds that it and the previous versions of RevitaLash are drugs under the FDCA and the Cal. Healthy and Safety code.

C. New Drug, Misbranding, and UCL

Athena argues that RevitaLash Advanced is not a new drug because it is not a drug and therefore cannot be a drug intended to grow hair. (Opp'n Br. 20.) Since the Court has found that all of Athena's RevitaLash products are drugs in the meaning of the statutes because they are intended to grow hair, they are per se new drugs. 21 C.F.R. § 310.527(a); Cal. Health and Safety Code § 110110.

Athena acknowledges that it has not filed an application for approval of its products as new drugs or met the numerous requirements associated with this classification. (SUF ¶ 12.) Thus, Athena violates 21 U.S.C. § 355(a) and Cal. Health and Safety Code § 111550 as part of its business

practices. Additionally, it violates Cal. Health and Safety Code §§ 110398, 111440 by selling misbranded products. Finally, the uncontroverted facts have established that Athena is a competitor of Allergan's and that RevitaLash products specifically compete with Latisse, establishing injury in fact as pled. Section III. C. 2., III. D. *supra* p. 7-8; (SUF ¶¶ 61-63). Therefore, the Court finds that Allergan has established its fourth cause of action for violation of the UCL beyond a genuine issue of fact.

V. CONCLUSION

For the foregoing reasons. The motion for partial summary judgment is GRANTED.

IT IS SO ORDERED.

APPENDIX E — OPINION OF THE UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA, FILED MAY 16, 2012

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES – GENERAL

SACV 07-01316-JVS (RNBx) Consolidated
with SACV 08-427 and SACV 09-328

Allergan Inc.

v.

Athena, *et al.*

Date May 16, 2012

Present: The Honorable James V. Selna

Karla J. Tunis	Not Present
Deputy Clerk	Court Reporter

Attorneys Present for Plaintiffs: Not Present
Attorneys Present for Defendants: Not Present

Proceedings: **(IN CHAMBERS) Order DENYING Defendants Athena Cosmetics, Inc., Pharma Tech International, Inc., and Northwest Cosmetic Laboratoreis, LLC's Motion for Partial Judgment**

on the Pleadings (Fld 3-23-12. #639); Defendants Lifetech Resources & Rocasuba, Inc's Partial Joinder in Defendants Athena Cosmetics, Inc., Pharma Tech International, Inc., and Northwest Cosmetic Laboratories, LLC's Motion for Partial Summary Judgment on the Pleadings (Fld 3-27-12, #641) and Defendants Cosmetic Alchemy, LLC, Metics, LLC, Product Innovations, LLC, Stella International LLC's Joinder in Motion for Partial Summary Judgment at docket 639 (Fld 4-17-12, #647); AND Order SETTING NEW HEARING on **Plaintiffs' Motion for Partial Summary Judgment Against Defendant Athena Cosmetics, Inc. On Allergan's Fourth Claim for Relief (Fld 3-19-12**, #628 & 630).

The present action involves several claims and counter-claims regarding eyelash and hair products. Plaintiff and counter-defendant Allergan, Inc. ("Allergan") filed a motion for partial summary judgment on its fourth claim for relief against Athena Cosmetics, Inc. on March 16, 2012. (Docket No. 628.) The motion was originally set to be heard on April 16, 2012. In light of a forthcoming related motion, the parties stipulated and the Court ordered Allergan's motion and the defendants' anticipated motion on the fourth claim for relief to be heard on May 7, 2012. (Sched. Order, Docket No. 638.)

Appendix E

Defendants and counter-claimants Athena Cosmetics, Inc.; Northwest Cosmetic Laboratories, LLC; and Pharma Tech International, Inc. (collectively "Athena") filed the anticipated motion for judgment on the pleadings with respect to Allergan's fourth, fifth, and sixth claims for relief on March 23, 2012 to be heard May 7, 2012. (Docket No. 639.) Defendants Lifetech Resources, LLC and Roscasuba, Inc. (collectively"Lifetech") filed a partial joinder in Athena's motion for judgment on the pleadings on March 27, 2012. (Docket No. 641.) They joined in Athena's second argument. *Id.* Defendants Cosmetic Alchemy, LLC; Metics, LLC; Product Innovations, LLC; and Stella International, LLC filed a joinder in Athena's motion on April 17, 2012. (Docket No. 647.) Defendants Peter Thomas Roth, Inc. and Peter Thomas Roth Labs, LLC filed their joinder in the same motion on April 19, 2012. (Docket No. 652.)

The Court continued both motions to May 14, 2012. (Docket No. 673.) Allergan timely opposed the motion for judgment on the pleadings and Athena and Lifetech filed replies. Allergan filed an objection and response to Lifetech's partial joinder. Athena timely opposed the motion for partial summary judgment, and Allergan replied. For the following reasons the motion for judgment on the pleadings is DENIED. The Court sets a hearing for additional argument on the motion for partial summary judgment on June 11, 2012.

Appendix E

I. LEGAL STANDARD

Under the Rule 12(c), "[a]fter the pleadings are closed but within such time as not to delay the trial, any party may move for judgment on the pleadings." Judgment on the pleadings is appropriate when, taking all the allegations in the pleadings as true, the moving party is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 12(c); *Fleming v. Pickard*, 581 F.3d 922, 925 (9th Cir. 2009). Thus, a motion for judgment on the pleadings is governed by the same standard as a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6). *Aldabe v. Aldabe*, 616 F.2d 1089, 1093 (9th Cir. 1980).

Under Rule 12(b)(6), a defendant may move to dismiss for failure to state a claim upon which relief can be granted. A plaintiff must state "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim has "facial plausibility" if the plaintiff pleads facts that "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (May 18, 2009).

In resolving a Rule 12(b)(6) motion under *Twombly*, the Court must follow a two-pronged approach. First, the Court must accept all well-pleaded factual allegations as true, but "[t]hread-bare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* Nor must the Court "accept as true a legal conclusion couched as a factual allegation." *Id.* at 1949-50 (quoting *Twombly*, 550 U.S. at 555). Second, assuming

the veracity of well-pleaded factual allegations, the Court must "determine whether they plausibly give rise to an entitlement to relief." *Id*. at 1950. This determination is context-specific, requiring the Court to draw on its experience and common sense, but there is no plausibility "where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct." *Id.*

II. STANDING

The Court first turns first to the statutory standing issue. Athena argues that because Allergan has not pled that it actually relied on Athena's actions, it has no standing to assert a claim under California Business and Professions Code § 17200 *et seq.* (the "UCL"). (JOP Mot. Br. 7, Docket No. 640.)[1] Therefore, Athena contends, it is entitled to judgment on Allergan's fourth claim for relief which alleges all defendants violated the UCL. (*Id.*)

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1. Paragraph K of the Court's Initial Order in this case states that "[n]o footnote shall exceed 5 lines . . . . All footnotes shall be in the same type size as text. (Initial Order 7, Docket No. 5.) Athena's initial and reply memoranda of points and authorities ("MPA") in support of its motion for judgment on the pleadings and its MPA in opposition to Allergan's motion for partial summary judgment violate this order, as the footnotes are in a smaller type size than the text and at least one exceeds the five-line limitation. (*See* Docket Nos. 640, 649, 665 n. 5.) The Initial Order goes on to state that "[f]ailure to follow these requirements may result in rejection of a brief for correction." (Initial Order 7.) Because it does not appear that Athena is attempting to avoid the page limitations of the Local Rules, the Court chooses not to reject theses briefs, but cautions Athena to conform to the Court's order in future filings.

Appendix E

Athena argues that Allergan's cause of action requires actual reliance to be pled in order to have standing because the cause of action is based on misrepresentation or deception. (*Id.*) It contends that this argument is distinct from the issue raised previously in this Court's grant of judgment on the pleadings for this claim, the subsequent appeal, and reversal. (*Id.*) Further, it argues that to the extent Allergan bases its UCL claim on unlawful conduct, it must still show actual reliance because the alleged unlawful conduct is based on misrepresentations. (JOP Rep. Br. 3, Docket No. 665.)

Allergan argues that because its UCL claim is not based on misrepresentation or deception but "on pure statutory violations wholly independent of the veracity of statements made to consumers" it need not plead reliance. (JOP Opp. Br. 10, Docket No. 643.) It points out that deception of consumers is not an element of liability for many of the alleged statutory violations and that the misbranding violations are also not premised on actual misrepresentation. (*Id.* at 11-12.) Allergan further argues that these violations are not based on misrepresentation because the veracity of the advertising or labeling that triggers the violations is irrelevant to establishing those violations. (*Id.* at 12.) Finally, Allergan also argues that this argument is simply a relitigation of the issue the Federal Circuit addressed on appeal and therefore this Court is bound by the law of the case doctrine to reject this argument. (*Id.* at 13-14.)

Appendix E

A. UCL Standards

"The UCL's purpose is to protect both consumers and competitors by promoting fair competition in commercial markets for goods and services." *Kasky v. Nike, Inc.*, 27 Cal.4th 939, 949 (2002). The scope of the act is broad. *Id.* It prohibits "any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising and any act prohibited by [California's False Advertising Law]." Bus. & Prof. Code § 17200. In order to bring an action under the UCL, a private party must have "suffered injury in fact and ha[ve] lost money or property as a result of the unfair competition." Bus. & Prof. Code § 17204. A claim under the UCL against a party for an unlawful business practice can be based on any act or practice committed pursuant to business activity that is forbidden by law, whether federal state or local. *Hale v. Sharp Healthcare*, 183 Cal. App. 4th 1373, 1382-83 (2010).

The parties do not dispute that Allergan has sufficiently alleged an injury in fact. (JOP Mot. Br. 7.) They dispute whether Allergan has sufficiently met the second requirement, that its injury is a result of the alleged unfair competition. A UCL action predicated on fraudulent business practice requires reliance on that practice in order to meet this causation element. *In re Tobacco II Cases*, 46 Cal.4th 298, 326 (2009). This requirement also applies to a UCL action predicated on unlawful business practices or acts when "the unlawful conduct is misrepresentation." *Hale*, 183 Cal. App. 4th at 1385. If "[a] UCL violation . . . is not based on a 'fraud theory involving false advertising and misrepresentations

to consumers' [it] does not require a showing of reliance or causation." *Galvan v. KDI Distribution, Inc.*, 2011 WL 5116585 at *9 (C.D. Cal. Oct. 25, 2011) (quoting *Tobacco II*, 46 Cal.4th at 326 n. 17).

B. Law of the Case

The Court previously granted judgment on the pleadings to Athena and defendants for lack of standing because it had not plead an injury compensable by restitution. *Allergan, Inc. v. Athena Cosmetics, Inc.*, 640 F.3d 1377, 1380 (Fed. Cir. 2011). Allergan appealed. *Id.* At the Federal Circuit, Athena argued that Allergan lacked standing both because it did not allege a restitution eligible injury and because Allergan had no business dealings with the defendants. *Id*. at 1382. The Federal Circuit reversed and remanded to the Court for "further proceedings consistent with this opinion." *Id*. at 1384. It recognized that a change in the injury requirements of California law removed the restitution eligible requirement. *Id*. at 1382. It held that "Allergan's complaint sufficiently alleges an injury that was caused by the defendants' unfair business practices. Under *Kwikset*, this satisfies the requirements of section 17204, and therefore Allergan has standing to pursue its claim for relief under the UCL." *Id*. (discussing *Kwikset Corp. v. Superior Court*, 51 Cal. 4th 310, 335-36). The Federal Circuit went on to reject the purported "business dealings" requirement argument. *Allergan*, 640 F.3d at 1383. It held that "[t]he only standing requirements under 17204 are those in the language of the statute and, as explained in I.B., Allergan has satisfied those requirements." *Id*.

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Athena argues the statements referring to whether Allergan's allegations meet the causation requirement are dicta and the Federal Circuit only addressed whether a party must allege an injury compensable by restitution to have standing. (JOP Mot. Rep. Br. 6.) It argues that actual reliance "is an independent standing requirement under the UCL" that was unaddressed. (*Id.*) This stands in direct contradiction with the opinion quotations above.

The law of the case doctrine is often discussed in terms of issues decided previously by "the same court, or a higher court in the identical case," *Richardson v. United States*, 841 F.2d 993, 996 (9th Cir.), *amended*, 860 F.2d 357 (9th Cir.1988), and this doctrine is recognized as discretionary. *Milgard Tempering, Inc. v. Selas Corp. of America*, 902 F.2d 703, 715 (9th Cir. 1990). Athena cites, cases discussing this doctrine. (JOP Rep. Br. 6 (citing *Thomas v. Bible*, 983 F.2d 152, 154 (9th Cir. 1993); *Milgard*, 902 F.2d at 715).)

Related, and sometimes referred to as law of the case but also referred to as law of mandate states that "[w]hen a case has been decided by an appellate court and remanded, the court to which it is remanded must proceed in accordance with the mandate and such law of the case as was established by the appellate court. *Firth v. United States*, 554 F.2d 990, 993 (9th Cir. 1977). This doctrine is also slightly flexible, but "a mandate is controlling as to all matters within its compass, while leaving any issue not expressly or impliedly disposed of on appeal available for consideration by the trial court on remand." *Id.* at 994. This is true even if the mandate was in error. *Id.*

Here, the Court is confronted with the explicit language of the Federal Circuit that Allergan's complaint "sufficiently alleges an injury *that was caused* by the defendants' unfair business practices." *Allergan*, 640 F.3d at 1382 (emphasis added). It recognized that the standing inquiry had both injury and causation factors. *Id.* Further, it expressly stated that all standing requirements under § 17204 were met. *Id.* In light of this explicit language and the similarity of a purported business dealing requirement and reliance, the Court believes this matter is within the compass of the Federal Circuit mandate. Accordingly, Allergan has sufficiently pled injury and causation to have standing to pursue its UCL claim.

III. PRIMARY JURISDICTION ANALYSIS

Athena alternatively argues that the UCL claim and the fifth and sixth claims should be dismissed without prejudice or stayed because they require determination of whether Athena's RevitaLash® products are drugs or cosmetics. (JOP Mot. Br. 11.) It argues that the Federal Drug Administration ("FDA") or the California State Department of Health Services ("CSDHS") should makes that determination. (*Id.* at 11-12.)

Allergan argues that application of the primary jurisdiction doctrine is purely discretionary. (JOP Opp. Br. 16.) It argues the Court should not apply it here where the issue involved is a type ordinarily resolved by a court, an administrative agency has no particular expertise with regard to the issues, and the issues do not require the application of complex regulations. (*Id.*) Further, it argues

that possible delay or lack of an administrative remedy weigh against application. (*Id*.)

A. Standard

"The primary jurisdiction doctrine allows courts to stay proceedings or to dismiss a complaint without prejudice pending the resolution of an issue within the special competence of an administrative agency." *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008). By doing so, a court "enables" referral to the agency. *Id*. at 1115. This means only that the parties are enabled to "seek an administrative ruling." *Syntek Semiconductor Co., Ltd. v. Microchip Technology Inc.*, 307 F.3d 775 782 n. 3 (9th Cir. 2002). "[T]he parties are responsible for initiating administrative proceedings themselves." *Id*. The doctrine is not jurisdictional, but prudential, where "a court determines that an otherwise cognizable claim implicates technical and policy questions that should be addressed in the first instance by the agency with regulatory authority over the relevant industry, rather than by the judicial branch." *Clark*, 523 F.3d at 1114.

Although there is no set formula for analysis, the factors to consider include: "(1) a 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 authority that (4) requires expertise or uniformity in administration." *Id*. at 1115.

C. Determination at Issue

The determination at issue is whether or not RevitaLash® products are drugs or cosmetics.[2] Athena contends this determination requires "extensive fact-based chemical and pharmacological determinations." (JOP Mot. Br. 11.) However, just pages earlier Athena recognizes that "the intended use or effect of a product–and not the product's physical properties–determines whether a product is a drug or a cosmetic." (*Id*. at 8-9.) Allergan specifically argues and alleges that the RevitaLash® products are drugs because they are intended to grow eyelashes.

For the purposes of the relevant statutes substances are drugs if they are "(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. (g)(1). Allergan asserts the RevitaLash® products are drugs under section (B). Vendor intent is key for this category and this intent may be derived or inferred from labeling, promotional material, advertising, or any other relevant source. *U.S. v. Storage Spaces Designated Nos. 8 and 49 Located at 277 East Douglas, Visalia, Cal.*, 777 F.2d 1363, 1366 (9th Cir. 1985).

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2. To the extent other defendants join Athena's motion, the Court discusses the joinder in Section VI *infra*.

While the alleged statutory violations also require that Athena's products be "new drugs" under the Federal Food, Drug, and Cosmetic Act ("FDCA"), this determination is not really at issue here. 21 U.S.C. § 321(p). Under 21 C.F.R. § 310.527(a), incorporated by California Health and Safety Code § 110110, any OTC drug purportedly for growing hair is a new drug per se for purposes of the FDCA. Here, Allergan appears to only pursue that Athena's products are drugs based on an intended use to grow hair, therefore if they are considered drugs, they would be new drugs. Thus, cases going to the level of expertise required in determining whether a drug is a new drug, are not applicable here. *E.g., Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973).

D. Application

Considering the non-exclusive factors discussed above, only one appears to be in dispute. There is clearly an issue that needs to be resolved. Allergan does not dispute this issue falls under the FDA and the CSDHS authority. (JOP Opp. Br. 15-19.) The drug and cosmetic industry are regulated according to comprehensive regulatory schemes, the FDCA and the California Sherman Act. The primary dispute centers on the fourth factor, whether it requires expertise or uniformity in administration. As an additional factor, Allergan argues that the current status of administrative action weighs in favor of not staying or dismissing claims based on this matter.

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1. Expertise or Uniformity in Administration

Several of Athena's alleged determinations requiring expertise are not actually at issue here. (JOP Mot. Br. 12-13 (discussing safety determinations about its products).) However, it also contends that the FDA and CSDHS are the better entity to review the permissible language used in marketing RevitaLash®, which does go to the determination at issue. (*Id.* at 14.) It primarily relies on *Estee Lauder, Inc. v. U.S. Food & Drug Admin.*, 727 F.Supp. 1, 4 (D.D.C., 1989), where the Court dismissed the action on ripeness grounds. In doing so, it commented that determining the intended use of each product at issue based on the labeling and advertising in the past and present was a factual determination that the FDA should take on and determine before the Court due to its expertise. *Id.*

Allergan contends that the determination is a simple factual determination that courts are not only capable of determining but better equipped to do so. (JOP Opp. Br. 17.) It argues that the determination is non-technical because it does not require evaluation of the accused products physical properties or effects, only intent. (*Id.*) Allergan asserts that intent determinations require no agency expertise and courts are frequently called on to make such determinations. (*Id.*)

Both parties spend significant time distinguishing each other's authority. (*See Id.* at 18; JOP Rep. Br. 13.) As Athena points out, Allergan's primary authorities involve application of an agency determination (*In re Farm Raised*

Salmon Cases, 42 Cal.4th 1077, 1085 (2008)), or did not involve causes of action under the FDCA, only related ones (*Pom Wonderful LLC v. Ocean Spray Cranberries, Inc.*, 642 F. Supp. 2d 1112, 1117 (C.D. Cal. 2009)). (JOP Rep. Br. 13-14.) As Allergan points out, Athena's authorities either go to determinations not at issue here (*Weinberger*, 412 U.S. at 647), or do not involve primary jurisdiction (*Estee Lauder*, 727 F.Supp. at 4). (JOP Opp. Br. 18.)

Lifetech has requested judicial notice of an FDA warning letter it received and other correspondence.[3] (RJN 2, Docket No. 661.) It argues that these documents help demonstrate the expertise that the agency exerts in making the determination at issue here. (Lifetech Rep. Br. 4, Docket No. 660.) It considers the packaging and marketing claims of a products, along with the ingredients of a product and possible safety concern. (*Id.*) Further,

3. Allergan opposes the Court's consideration of this material and Lifetech's separate reply brief for the motion for judgment on the pleadings in its papers. (Allergan Obj. and Resp. to Joinder 2, Docket No. 671.) However, at oral argument Allergan referenced the FDA warning letter in support of its position several times. Lifetech asserted that it provided the documents and argument in response to arguments Allergan made in its opposition. In its objection, Allergan also acknowledges that Lifetech "parrots Athena's argument" and relied on cases "similar to Athena." (*Id.* at 3.) The Court finds that with the filing of its Joinder of the motion, Lifetech put Allergan on notice that the motion would also be dealing with Lifetech for purposes of primary jurisdiction. Additionally, the arguments do not appear so far abroad that they are beyond the current briefing before the Court. The Court therefore considers the reply brief and takes judicial notice of the provided documents pursuant to Fed. R. of Evid. 201.

Lifetech argues that this letter shows the benefit and ongoing nature of the administrative agency process. (*Id.* at 7-8.) Upon receipt of this letter, Lifetech was able to correct several deficiencies and report so to the FDA without penalization. (*Id.* at 8.) It claims this practice is part of the agency expertise, and shows why the agency is better suited to undertake an analysis of all facets of cosmetic ingredient and marketing issues. (*Id.*)

Any level of expertise required to make the present determination is not the type that is beyond the Court or more likely found in an administrative agency. Nor is that expertise so great that the Court should defer to a possible agency determination. As the Court described above, the determination at issue is solely one of objective intent. There are no pharmacological or physical property determinations required. The fact that there are allegations about efficacy and safety in the complaint do not change what is required for the decision Athena seeks to stay for administrative decision.

Further, the only opinion seeming to lend credence to finding a need for agency expertise in such determinations arises in a district court under very different circumstances. In *Estee Lauder*, the FDA had engaged in administrative review of several cosmetics that were making claims it considered to be drug claims. 727 F.Supp. at 3. Estee Lauder and the FDA had exchanged correspondence about the FDA's view of the claims made about Estee Lauder's products, changes made by Estee Lauder, and the FDA possibly commencing enforcement actions. *Id.* Estee Lauder filed suit against the FDA seeking declaratory

relief. *Id.* The court found the action was not ripe for review because Lauder was asserting that the agency action was arbitrary and capricious but the action was not final. *Id.* at 4. In this context, the court found that the cause of action was not ripe in part because the issue was not fit for judicial decision because the decision was not final and involved several factual determinations. *Id.* This is the discussion to which Athena points to in order to support its position on expertise. The Court finds that the context of that decision is unhelpful for the present scenario. Here the Court is presented with a claim under state law. It does not involve a review of the arbitrariness and capriciousness of a non-final agency decision involving factual determinations. Therefore, the Court finds *Estee Lauder* unpersuasive here. Athena has not established that any expertise required to administer this standard is high enough to warrant this Court abstaining from making a decision

Further, the Court finds that the need for uniformity of administration is not strongly implicated. While many cosmetic products may use language similar to that used in Athena's current marketing, any decision by the Court would be highly dependent on the context surrounding the use of such language. *Estee Lauder*, 727 F.Supp. at 4 (discussing that a determination of intent is not dependent solely on the use of one or two words in product claims but also the context of that use, past labeling and advertising, and present labeling and advertising). A highly contextual determination for one set of products is unlikely to create uniformity in administration problems just from the fact a court makes a determination and an agency may make

others. To the extent uniformity in administration is achievable, it will be uniformity in the high level concepts, not in the more specific fact based context determinations. Therefore, the Court finds this factor does not favor staying the case.

2. Status of Current Administrative Action

Allergan makes much of the indeterminate state of current administrative action and whether the agencies will ever address the matter. (JOP Opp. Br. 19.) As a preliminary matter the Court notes that this doctrine acknowledge that administrative action is not guaranteed, does not require action to be currently underway, and only "enables" parties to seek action first. Additionally, Athena has provided a supplemental submission indicating ongoing state agency action investigating Athena's products. (Athena's Supp. Material, Docket No. 674.) Lifetech has argued there is current FDA action proceeding against it based on an FDA warning letter. (Lifetech Rep. Br. 8-11.) No defendants were able to supply any definite time horizon for when agency determination would occur or if it would ever occur. The Court finds that the status of current administrative action is so indeterminate that this weighs against staying or dismissing the case. *Farmer Ins. Exchange v. Superior Court*, 2 Cal.4th 377, 392 n. 9 (1992) (discussing delay as an appropriate factor to consider in applying the primary jurisdiction doctrine).[4]

4. Indeed, at oral argument, the parties referenced administrative inquiries going back to 2006 and 2007.

3. Conclusion on Primary Jurisdiction

Considering all the factors above, the Court declines to exercise its discretion under the doctrine to stay or dismiss the case.

IV. DISCONTINUED PRODUCTS

Athena also seeks dismissal of UCL claims directed to discontinued products because Allergan is not entitled to any relief for those claims. (JOP Mot. Br. 1.) It argues that under the UCL, one is entitled to only restitution or an injunction. (*Id.* at 16.) It has been established that Allergan is not eligible for restitution, and injunctive relief is only to prevent future harm. (*Id.*) Athena argues that because of this, no injunction can issue based on Athena's previous formulations of RevitaLash® without showing likely recurrence. (*Id.*) It contends that Allergan fails to do this because it has not alleged that Athena will market or produce earlier formulations in the future. (*Id.* at 17.) Further, the fact that this argument may go to the scope of an injunction does not prevent it from being considered now because if the broadest possible injunction could not reach the alleged misbehavior, then those claims must be dismissed.

Allergan argues that its UCL claim is not based on any specific formulation of RevitaLash® but instead based on the Athena's marketing etc. of "hair and/or eyelash growth products." (JOP Opp. Br. 19.) It points out that its complaint does not limit itself to formulations and argues that Athena's arguments better go to the scope

of a possible injunction, which is not currently before the Court. (*Id.* at 20-21.) Allergan argues that it is entitled to seek injunctive relief unless Athena can show there is no reasonable expectation that the wrong will be repeated. (*Id.*)

Under California law, a plaintiff cannot receive an injunction for past conduct unless he shows that the conduct will probably recur. *Sun Microsystems, Inc. v. Microsoft Corp*, 188 F.3d 1115, 1123 (9th Cir. 1999). However, using the similar methods to market the same or similar products is enough to show that probability. *People v. Toomey*, 157 Ca. App. 3d. 1, 20 (1984). Additionally, this instance is distinguishable from *Sun Microsystems* where all the accused conduct for the UCL violation had ceased because here UCL violations are alleged to continue, in the same field as purported past conduct. Any arguments to the proper scope of an injunction would be better analyzed after the adjudication of what violations have occurred, what violations are occurring, and how similar they are. Accordingly, the Court will not fracture and dismiss portions of Allergan's UCL claim.

V. OTHER CAUSES OF ACTION

Athena argues that because portions of the alleged false advertising violations in the fifth and sixth causes of action rely on a determination that its RevitaLash® products are drugs, they too should be dismissed. (JOP Mot. Br. 15.) Because the Court rejected the argument as applied to the fourth cause of action, it rejects it as applied to the fifth and sixth cause of action.

Appendix E

VI. OTHER DEFENDANTS

Allergan's fourth cause of action is asserted against all defendants. (Operative Compl. p. 15.) The fifth and sixth causes of action are only asserted against Athena. (*Id.* at p. 19, 20.) The fourth cause of action alleges that the "hair and/or eyelash growth products manufactured, marketed, sold and distributed by Defendants constitute 'drugs' under California and federal law. (*Id.* at ¶ 75.) Thus, the Court's reasoning applies to all defendants under this cause of action. Lifetech's provided evidence of current administrative action was already discussed and does not distinguish it in a material way. Therefore, the motion for judgment on the pleadings will be denied as to all joining defendants as well.

VII. SUMMARY JUDGMENT

Because the Court's tentative and the May 14, 2012 hearing did not touch significantly on Allergan's motion for partial summary judgment, the Court believes an additional hearing is in order. The Court will set a further hearing on the summary judgment motion.

VIII. CONCLUSION

For the foregoing reasons, the motion for judgment on the pleadings is DENIED. The motion for partial summary judgment is set for additional hearing on June 11, 2012 at 1:30 pm.

IT IS SO ORDERED

APPENDIX F — RELEVANT CONSTITUTIONAL, STATUTORY & REGULATORY PROVISIONS

United States Constitution, Article VI, Paragraph 2

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

Appendix F

21 U.S.C.S. § 321

§ 321. Definitions; generally

For the purposes of this Act [21 USCS §§ 301 et seq.]--

* * *

(g)

(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D) [21 USCS § 343(r)(1)(B) and (r)(3) or (r)(1)(B) and (r)(5)(D)], is made in accordance with the requirements of section 403(r) [21 USCS § 343(r)] is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with

section 403(r)(6) [21 USCS § 343(r)(6)] is not a drug under clause (C) solely because the label or the labeling contains such a statement.

* * *

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

* * *

(p) The term "new drug" means--

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the condition prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this

Act [enacted June 25, 1938] it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

* * * *

Appendix F

21 U.S.C.S. § 336

§ 336. Report of minor violations

Nothing in this Act [21 USCS §§ 301 et seq.] shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this Act [21 USCS §§ 301 et seq.] whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

Appendix F

21 U.S.C.S. § 337

§ 337. Proceedings in name of United States; provision as to subpoenas

(a) Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this Act [21 USCS §§ 301 et seq.] shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

(b)

(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of sections 401, 403(b), 403(c), 403(d), 403(e), 403(f), 403(g), 403(h), 403(i), 403(k), 403(q), or 403(r) [21 USCS § 341, 343(b), (c), (d), (e), (f), (g), (h), (i), (k), (q), or (r)] if the food that is the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1)--

(A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,

(B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or

(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

In any court proceeding described in subparagraph (C), a State may intervene as a matter of right.

Appendix F

21 U.S.C.S. § 355

§ 355. New drugs

(a) Necessity of effective approval of application. 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) is effective with respect to such drug.

Appendix F

21 U.S.C.S. § 360K

§ 360k. State and local requirements respecting devices

(a) General rule. Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--

(1) which is different from, or in addition to, any requirement applicable under this Act [21 USCS §§ 301 et seq.] to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act [21 USCS §§ 301 et seq.].

(b) Exempt requirements. Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if--

(1) the requirement is more stringent than a requirement under this Act [21 USCS §§ 301 et seq.] which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement--

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this Act [21 USCS §§ 301 et seq.].

Appendix F

21 C.F.R. 201.128

§ 201.128 Meaning of "intended uses."

The words "intended uses" or words of similar import in §§ 201.5, 201.115, 201.117, 201.119, 201.120, and 201.122 refer to the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the drug, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put.

Appendix F

CAL. HEALTH & SAFETY CODE § 109900

§ 109900. "Cosmetic"

"Cosmetic" means any article, or its components, intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to, the human body, or any part of the human body, for cleansing, beautifying, promoting attractiveness, or altering the appearance.

The term "cosmetic" does not include soap.

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CAL. HEALTH & SAFETY CODE § 109925

§ 109925. "Drug"

"Drug" means any of the following:

(a) Any article recognized in an official compendium.

(b) Any article used or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or any other animal.

(c) Any article other than food, that is used or intended to affect the structure or any function of the body of human beings or any other animal.

(d) Any article used or intended for use as a component of any article designated in subdivision (a), (b), or (c) of this section.

The term "drug" does not include any device.

Any food for which a claim (as described in Sections 403(r)(1)(B)(21 U.S.C. Sec. 343(r)(1)(B)) and 403(r)(3)(21 U.S.C. Sec. 343(r)(3)) or Sections 403(r)(1)(B)(21 U.S.C. Sec. 343(r)(1)(B)) and 403(r)(5)(D)(21 U.S.C. Sec. 343(r)(5)(D)) of the federal act), is made in accordance with the requirements set forth in Section 403(r)(21 U.S.C. Sec. 343(r)) of the federal act, is not a drug under subdivision (b) solely because the label or labeling contains such a claim.

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CAL. HEALTH & SAFETY CODE § 111550

§ 111550. Requirements for sale

No person shall sell, deliver, or give away any new drug or new device unless it satisfies either of the following:

(a) It is one of the following:

(1) A new drug, and a new drug application has been approved for it and that approval has not been withdrawn, terminated, or suspended under Section 505 of the federal act (21 U.S.C. Sec. 355).

(2) A new biologic product for which a license has been issued as required by the federal Public Health Service Act (42 U.S.C. Sec. 262).

(3) A device that is reported under Section 510(k) of the federal act (21 U.S.C. Sec. 360(k)), or is a device exempted pursuant to subsection (*l*) or (m) of Section 360 of Title 21 of the United States Code, or it is a new device for which a premarket approval application has been approved, and that approval has not been withdrawn, terminated, or suspended under Section 515 of the federal act (21 U.S.C. Sec. 360e).

(b) The department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended. Any person who files a

new drug or device application with the department shall submit, as part of the application, all of the following information:

(1) Full reports of investigations that have been made to show whether or not the new drug or device is safe for use and whether the new drug or device is effective in use under the conditions prescribed, recommended, or suggested in the labeling or advertising of the new drug or device.

(2) A full list of the articles used as components of the new drug or device.

(3) A full statement of the composition of the new drug or device.

(4) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the new drug, or in the case of a new device, a full statement of its composition, properties, and construction, and the principles of its operation.

(5) Samples of the new drug or device and of the articles used as components of the drug or device as the department may require.

(6) Specimens of the labeling and advertisements proposed to be used for the new drug or device.

Appendix F

CAL. HEALTH & SAFETY CODE § 111840 (2014)

§ 111840. Commencement of actions

The Attorney General, any district attorney, or any city attorney to whom the department reports any violation of this part shall begin appropriate proceedings in the proper court.

Appendix F

CAL. BUS. & PROF. CODE § 17200

§ 17200. Definition

As used in this chapter, unfair competition shall mean and include any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising and any act prohibited by Chapter 1 (commencing with Section 17500) of Part 3 of Division 7 of the Business and Professions Code.