IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
GAINESVILLE DIVISION

GRACEWAY PHARMACEUTICALS, LLC and CHESTER VALLEY PHARMACEUTICALS, LLC,	:	
Plaintiffs,	:	CIVIL ACTION NO. 2:08-CV-0067-RWS
v.	:	
RIVER'S EDGE PHARMACEUTICALS, LLC,	:	
Defendant.	:	

ORDER

This case is before the Court on Defendant's Motion for Summary Judgment [129], Defendant's Motion to Compel Discovery [105], Defendant's Emergency Motion to Extend Discovery for Limited Purposes [109], Defendant's Motion for Leave to File Amended Motion [181], and Plaintiff's Motion for Leave to File a Surreply Brief in Opposition to Defendant's Motion for Summary Judgment [177]. After reviewing the entire record, the Court enters the following order.

I. Defendant's Motion for Summary Judgment [129]

Background

Graceway Pharmaceuticals and Chester Valley Pharmaceuticals (collectively "Graceway" or "Plaintiffs"), brought this action against River's Edge Pharmaceuticals ("River's Edge" or "Defendant") asserting claims of false advertising and unfair competition. (Complaint [1] at ¶ 1). Graceway markets prescription benzoyl peroxide products under the Benziq trademark for the treatment of acne. (Id.; SMF[1] at ¶ 8). Defendant, under the Benprox label, also markets a benzoyl peroxide product for the treatment of acne. (SOF[2] at ¶ 1). Benprox was created specifically to compete with Benziq. (SMF at ¶¶ 11, 17). Both Benziq and Benprox are available as a 5.25 percent wash and a 5.25 and 2.75 percent gel.[3] (SMF at ¶ 8; SOF at ¶ 1).

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[1] Plaintiffs' Statement of Additional Material Facts that Present a Genuine Issue for Trial ("SMF") [156] in response to Defendant's Motion for Summary Judgment.

[2] Defendant's Statement of Facts in Support of Motion for Summary Judgment ("SOF") [131-1].

[3] The percent refers to the percentage of the active ingredient benzoyl peroxide contained in each product.

Plaintiffs' complaint arises out of what it refers to as "River's Edge's false and misleading promotion of its benzoyl peroxide gels and wash products as generically equivalent or otherwise substitutable" for Plaintiffs' Benziq products. (Complaint at ¶ 1). Plaintiffs assert that Defendant has made false representations about the nature and characteristics of Benprox. These alleged misrepresentations can be placed into two categories: 1) Defendant falsely claims that Benprox is equivalent to, or substitutable for, Benziq; and 2) Defendant makes false representations on Benprox's label in regards to the active ingredient strength, dosage form, and expiration date.

Plaintiffs' causes of action include violations of the Lanham Act, which provides a private remedy to a plaintiff harmed by "commercial advertising or promotion" that "misrepresents the nature, characteristics, [or] qualities . . . of his or her or another person's goods." 15 U.S.C. § 1525(a)(1)(B). In order to successfully allege a Lanham Act violation for false advertising or unfair competition, Plaintiffs must identify the "commercial advertising or promotion" that they contend misrepresents the nature, characteristics or qualities of

Defendant's product.[4] Plaintiffs point to two forms of communication as purportedly misrepresenting Benprox's equivalence or substitutability for Benziq.

The first type of communication involves new product submission forms sent by Defendant to various pharmaceutical databases. (SMF at ¶¶ 25, 27). These pharmaceutical databases are a key component of most retail pharmacy dispensing systems. (Id. at ¶ 23). Plaintiffs commissioned a survey of pharmacists in which 99 percent of respondents used a pharmaceutical database to look up drugs and brand names. (Id. at ¶ 151). Therefore, it was critical to the sale of Benprox, that it be listed as a generic or equivalent drug to Benziq in these databases. (Id. at ¶ 28). The forms submitted to the First DataBank and Wolters Kluwer databases represented that Benprox was available in 2.75 or 5.25 percent strength and was available in wash or gel dosage form. (Id. at ¶¶ 25, 27). As a result of these submissions, Benprox was linked with Benziq in these pharmaceutical databases. (Id. at ¶ 26).

[4] This is not a case in which Plaintiffs contend that Defendant directly misrepresented the characteristics of Plaintiffs' product, Benziq.

Defendant maintains that its submissions to pharmaceutical databases occurred on standardized forms and did not include any claims that Benprox is generic or equivalent to Benziq, and did not even mention Benziq by name. (SOF at ¶¶ 3-5). However, once the two products were linked in pharmaceutical databases, Defendant did contact pharmacies and drug distributors to market Benprox as a substitute for Benziq. (SMF at ¶¶ 31-33, 36-38). Defendant also entered into several drug supply agreements with drug wholesalers to increase the sale of Benprox relative to Benziq. (SMF at ¶¶ 39-42).

The second form of communication that Plaintiffs point to as false advertising by the Defendant is a flyer submitted to Kinray, a wholesale distributor of generic drugs, for distribution to its customers. (Id. at ¶ 48). The Kinray flyer for Benprox contained the headline: "Get your money-saving, quality River's Edge generic products through Kinray today." (Id. at ¶¶ 48, 49). The flyer promoted the 5.25 percent Benprox wash and gel as products that "compete[] with" the Benziq wash and gel. (Id. at ¶¶ 48, 50). Defendant contends that the flyer was prepared in the format prescribed by Kinray, and that Kinray supplied the headline and the table heading, "competes with." (SOF

at ¶¶ 11, 15). Defendant also included a disclaimer on the flyer that River's Edge products, unless noted otherwise, do not claim bioequivalence[5] to products it "competes with."[6] (SOF at ¶¶ 16, 7).

Plaintiffs allege that Defendant used its new product submission forms and its communications with pharmaceutical databases and distributors to falsely imply that Benprox is equivalent to or substitutable for Benziq. In the survey of pharmacists conducted by Plaintiffs, 39 percent of respondents stated that when a database shows that a benzoyl peroxide drug is linked to a specific brand name, it means that the drug is a generic equivalent of the brand name drug. (SMF at ¶ 152). Defendants contend that Plaintiffs' survey was flawed, among other reasons, because it did not specify that the question was in regards to unrated, topical benzoyl peroxide products like Benziq and Benprox. (SOF at ¶ 27).

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[5] A drug is bioequivalent to another if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug" when administered in the same dose under similar conditions. 21 U.S.C. § 355(j)(8)(B)(i).

[6] The e-mail transmittal sheet accompanying the New Product Submission Form also contained the note disclaiming bioequivalence. (SOF at ¶ 7).

It is important to note that neither Benziq nor Benprox has been tested or approved by the United States Food and Drug Administration ("FDA").[7] (SOF at ¶ 20, 22). In order for a drug to be approved by the FDA, it must be the subject of either a New Drug Approval application ("NDA") or an Abbreviated New Drug Approval application ("ANDA"). An ANDA is used to gain approval for a generic version of a drug for which the FDA has already approved an NDA. The FDA publishes a listing of Approved Drug Products with Therapeutic Equivalence Evaluations, known as the Orange Book. (SOF at ¶ 21). The Orange Book contains drugs approved by the FDA and their approved generic equivalents. (Id.). Because neither Benziq nor Benprox has been subject to the FDA approval process, neither is listed in the Orange Book, and the FDA does not make any determination as to the equivalency of the two drugs.

[7] While neither Benziq or Benprox have undergone the FDA approval process, they are still drugs that fall under the purview of the FDCA. The FDCA defines drugs as, among other things, "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." 21 U.S.C. § 321(g)(1)(B). Both Benziq and Benprox are designed and used for the treatment of facial acne. (SMF at ¶ 8; SOF at ¶ 1).

Therefore, determining whether one is substitutable for the other is based on state law. Drug substitutions in Georgia are regulated by the Georgia Pharmacy Practice Act ("GPPA"), O.C.G.A. § 26-4-1, et seq. The GPPA allows a pharmacist to substitute a drug that is "pharmaceutically equivalent" to the prescribed brand name drug product. O.C.G.A. § 26-4-81(a).[8] The statute defines "pharmaceutically equivalent" as "drug products that contain identical amounts of the identical active ingredient, in identical dosage forms, but not necessarily containing the same inactive ingredients." O.C.G.A. § 26-4-5(27). Therefore, in order to substitute Benprox for Benziq in Georgia, a pharmacist does not need to determine that one drug is generic for the other or that the two drugs are therapeutically equivalent.[9] Rather, the substitute drug need only

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[8] If a doctor prescribes a benzoyl peroxide wash or gel without specifying Benziq by brand name, a pharmacist in Georgia "*shall* dispense the lowest retail priced drug product which is in stock and which is, in the pharmacist's reasonable professional opinion, pharmaceutically equivalent." O.C.G.A. § 26-4-81(b) (emphasis added).

Benprox is less expensive than the comparable Benziq wash or gel. (SOF at ¶ 29). Therefore, if a physician prescribes, for example, a 5.25 percent benzoyl peroxide wash, and the pharmacy has both Benziq and Benprox in stock, the pharmacist must dispense Benprox.

[9] If a new drug is considered to be bioequivalent, *see note 5 supra*, then it is listed by the FDA in the Orange Book as therapeutically equivalent to, or generic for, the other drug. Ethex Corp. v. First Horizon Pharm. Corp., 228 F. Supp. 2d 1048, 1052 (E.D. Mo. 2002)

have: 1) the same active ingredient, 2) in the same strength, and 3) in the same dosage form as the prescribed medication.

The second strand of Plaintiffs' argument is that in addition to the false representations of equivalence between the two drugs, Defendant's assertions on the Benprox label as to the dosage form, active ingredient strength, and expiration date are also false.

Benprox is manufactured for River's Edge by Corwood Laboratories ("Corwood"). (SMF at ¶ 11). Concerns about the integrity of Corwood's manufacturing process underlie much of Plaintiffs' argument that Benprox is not properly substitutable for Benziq and also that the label is inaccurate in regards to Benprox's expiration date, dosage form, and active ingredient strength. (Id. at ¶¶ 72-80).

River's Edge lists a two-year expiration date for Benprox on its label, on deal sheets sent to distributors, and on each certificate of analysis. (SMF at ¶ 96-98). Plaintiffs engaged Dr. Steven Koepke to provide expert testimony in this case. (SMF at ¶ 59). As part of his analysis, Dr. Koepke found that Benprox failed stability testing due to a change in the drug's color, viscosity, gravity, and benzoyl peroxide strength. (Id. at ¶¶ 102-104, 107). He found that

the percentage of benzoyl peroxide fell below specifications six months into accelerated testing. (Id. at ¶ 104). Defendant counters that there is no evidence that the long-term stability of Benprox's color, viscosity, or gravity has any legal significance or is material. (Defendant's Reply Memorandum in Support of Summary Judgment ("Reply") [172] at 4). Dr. Koepke in his deposition acknowledged that the FDA does not require viscosity and gravity to be measured in a topical benzoyl peroxide product like Benprox. (Deposition of Steven R. Koepke, Ph.D, Oct. 28, 2008 ("Koepke Depo") [175] at 120:14-121:19). Dr. Koepke further acknowledged that a two-year expiration date is supported by meeting the active ingredient specifications three months into an accelerated test, as Benprox did. (Id. at 71:17-23). However, he still did not believe that Benprox warranted a two-year expiration date due to failures in viscosity, color, and specific gravity. (Id. at 71:24-72:9).

Plaintiffs also contend that River's Edge misrepresents that some of its products are gels, because Benprox fails to meet the FDA definition of a gel. (Plaintiffs' Response to Defendant's Motion for Summary Judgment ("Response") [142] at 9). The FDA Data Standards Manual defines a "gel" dosage form as a "semisolid dosage form that contains a gelling agent to

provide stiffness to a solution or a collodial dispersion." (SMF at ¶ 161). Furthermore, semisolids do not flow at low shear stress. (Id. at ¶ 164). However, Plaintiffs contend that shortcomings in the manufacturing process of Benprox gels caused the product to separate and run and behave "more like a lotion than a gel." (Response at 9). One of Defendant's experts acknowledged that some Benprox gel products do "flow like a liquid" and were "pourable." (SMF at ¶ 166). Defendant counters that Plaintiffs have only claimed that the Benprox gel does not meet the standard set forth in the FDA Data Standards Manual, but that Plaintiffs do not contend that Benprox has not met the standard set forth in the United States Pharmacopeia ("USP"), which requires that a benzoyl peroxide gel be in a "suitable gel base."[10]

Dr. Koepke also offered an opinion on the validity of the labeled strength of Benprox. He examined the test results reported on the certificates of analysis accompanying each batch of Benprox manufactured by Corwood to determine whether the amount of the active ingredient, benzoyl peroxide, contained in the

[10] The USP "is an official public standards–setting authority for all prescription and over–the–counter medicines and other health care products manufactured or sold in the United States." About USP - An Overview, http://www.usp.org/aboutUSP/. Dr. Koepke also acknowledges that the USP are "standards that are uniformly observed throughout the pharmaceutical industry." (SMF at ¶ 70).

batch matched what was represented on the Benprox label. (Id. at ¶¶ 60-62). Dr. Koepke concluded that the Benprox 5.25 percent wash is expected to contain between 90-110 percent of the amount of benzoyl peroxide listed on the label. (Id. at ¶ 63). For the 5.25 percent wash, five of the ten batches manufactured by Corwood contained benzoyl peroxide in excess of 110 percent of the labeled strength, with the strongest batch containing 120 percent of the labeled strength. (Id. at ¶ 60). The three batches of Benprox 5.25 percent gel ranged from 113 to 119 percent of the label strength, while the two batches of Benprox 2.75 percent gel contained 120 and 124 percent of the labeled benzoyl peroxide. (Id. at ¶¶ 61-62).

In response, Defendant first argues that Plaintiffs' claim of mislabeled strength is limited to the wash dosage form as Graceway does not identify an appropriate range of variation for the percentage strength of benzoyl peroxide in the gel dosage form. (Reply at 7-8). Further, Dr. Koepke acknowledges that there is no FDA or USP monograph for a benzoyl peroxide wash establishing the appropriate range for benzoyl peroxide strength. (Id. at 7). Second, Defendant argues that the FDA does not recognize "wash" as a dosage form at all, and for this Court to recognize wash as a dosage form would preempt the

FDA's decision-making.[11] (Id. at 8). Defendant argues that alternatively, this Court may observe the USP definition of a "benzoyl peroxide gel" as "benzoyl peroxide in a suitable gel base. It contains not less than 90.0 percent and not more than 125.0 percent of the labeled amount of benzoyl peroxide . . . ." (Id.). Since "wash" is not a dosage form recognized by the FDA and since Corwood describes the Benprox "wash" as an opaque gel,[12] Defendant argues that the Benprox wash is best viewed as a gel. Once viewed as a gel, Defendant argues that all of its batches of Benprox wash fall within the USP guidelines of a benzoyl peroxide gel, containing between 90 and 125 percent of the labeled benzoyl peroxide. (Reply at 8-9).

In light of its responses to Plaintiff's claims outlined above, River's Edge brings the present Motion for Summary Judgment asserting that there is no genuine issue as to any material fact and that River's Edge is entitled to judgment as a matter of law. The Court now examines Defendant's assertions.

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[11] See http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162038.htm (no listing of wash as a dosage form).

[12] The certificates of analysis examined by Dr. Koepke describe the appearance of Benprox wash as an opaque gel. (SMF at ¶ 60).

Discussion

Defendant has moved for summary judgment on both Plaintiffs' Lanham Act claims of false advertising and unfair competition, as well as Plaintiffs' common law claims of unfair competition and misappropriation.

Federal Rule of Civil Procedure 56 requires that summary judgment be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." FED. R. CIV. P. 56(c). "The moving party bears 'the initial responsibility of informing the . . . court of the basis for its motion, and identifying those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, which it believes demonstrate the absence of a genuine issue of material fact.'" Hickson Corp. v. N. Crossarm Co., 357 F.3d 1256, 1259 (11th Cir. 2004) (quoting Celotex Corp. v. Catrett, 477 U.S. 317, 323, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986) (internal quotations omitted)). Where the moving party makes such a showing, the burden shifts to the non-movant, who must go beyond the pleadings and present affirmative evidence to show that a genuine issue of

material fact does exist. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 257, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986).

The applicable substantive law identifies which facts are material. Id. at 248. A fact is not material if a dispute over that fact will not affect the outcome of the suit under the governing law. Id. An issue is genuine when the evidence is such that a reasonable jury could return a verdict for the non-moving party. Id. at 249-50.

In resolving a motion for summary judgment, the court must view all evidence and draw all reasonable inferences in the light most favorable to the non-moving party. Patton v. Triad Guar. Ins. Corp., 277 F.3d 1294, 1296 (11th Cir. 2002). But, the court is bound only to draw those inferences which are reasonable. "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no genuine issue for trial." Allen v. Tyson Foods, Inc., 121 F.3d 642, 646 (11th Cir. 1997) (quoting Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587, 106 S. Ct. 1348, 89 L. Ed. 2d 538 (1986)). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." Anderson, 477 U.S. at 249-50 (internal citations omitted); see also Matsushita, 475 U.S. at

586 (once the moving party has met its burden under Rule 56(c), the nonmoving party "must do more than simply show there is some metaphysical doubt as to the material facts").

With these standards as a foundation, the Court turns to address the merits of the Defendant's motions for summary judgment.

A. Lanham Act Claims

The purpose of the Lanham Act is to protect a business from a competitor's false advertising and to protect it from unfair competition by having its reputation and goodwill diverted. Natural Answers, Inc. v. SmithKline Beecham Corp., 529 F.3d 1325, 1331 (11th Cir. 2008); see also Mutual Pharm. Co. v. Ivax Pharms., Inc., 459 F. Supp. 2d 925, 933 (C.D. Cal. 2006) ("central focus of [Lanham Act] is to combat false representations in promoting a product in the marketplace"). The Lanham Act provides a private remedy to a plaintiff harmed by "commercial advertising or promotion" that "misrepresent the nature, characteristics, qualities or geographic origin of his or her or another person's goods, services or commercial activities."[13] 15 U.S.C. §

[13] The Lanham Act also creates a cause of action for unfair competition against any person who:

1125(a)(1)(B). In order to succeed on a false advertising claim under this section of the statute, a plaintiff must establish that:

> (1) the advertisements of the opposing party were false or misleading; (2) the advertisements deceived, or had the capacity to deceive, consumers; (3) the deception had a material effect on purchasing decisions; (4) the misrepresented product or service affects interstate commerce; and (5) the movant has been-or is likely to be-injured as a result of the false advertising.

Hickson Corp., 357 F.3d at 1260-61. Defendant maintains that its advertisements were not false or misleading and that they did not have the capacity to deceive, and even if deceptive, the ads did not have a material effect

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> uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which . . . is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person . . .

15 U.S.C. § 1125(a)(1)(A). Plaintiffs allege both Lanham Act false advertising and unfair competition claims, count one and two of the complaint, respectively. (Complaint at ¶¶ 43-61). The unfair competition claims is based on the same facts and actions that underlie the false advertising claim. The Lanham Act claims will primarily be examined through the false advertising framework, but the analysis is equally relevant and decisive as to the unfair competition claim.

on purchasing decisions by pharmacies. The Court now examines the nature and truthfulness of Defendant's advertisements.

1. Preclusion

Before discussing whether or not Defendant has made false assertions about Benprox's characteristics, this Court must determine whether the Lanham Act claims Plaintiffs assert are precluded by the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, et seq.[14] Defendant asserts that this Court cannot reach the issue of whether Benprox is what it claims to be, because of the preclusive effect of the FDCA. (Memorandum in Support of Motion for Summary Judgment ("Def.'s Memo") [129-1] at 8-10).

Both the Lanham Act and the FDCA regulate the marketing of prescription drugs. While the Lanham Act is "primarily intended to protect commercial interests" from being harmed by the unfair competition caused by a competitor's false or misleading advertising, the FDCA protects the public by

[14] The relevant issue is preclusion and not preemption. Preemption is based on the Supremacy Clause of the United States Constitution, and involves the interplay between federal and state laws. Preclusion, on the other hand, involves the relationship and interaction between two federal laws. Pediamed Pharms., Inc. v. Breckenridge Pharm., Inc. 419 F. Supp. 2d 715, 722 n.12 (D. Md. 2006).

ensuring that drugs sold in the marketplace are safe, effective, and not misbranded. Mutual Pharm. Co., 459 F. Supp. 2d at 933 (C.D. Cal. 2006) (quoting Sandoz Pharms. v. Richardson-Vicks, Inc., 902 F.2d 222, 230 (3d Cir. 1990)). Neither statute contains provisions that expressly preclude the other from operating within the regulatory space in which they overlap. Id. However, courts have been wary of allowing Lanham Act claims where determining the falsity of the representation at issue would require the court to interpret and then apply the regulatory or statutory provisions of the FDCA. Id. at 934. But, simply because a term is regulated by the FDCA or a matter touches upon an area dealt with by the FDA does not serve as an automatic bar to Lanham Act claims. Schwarz Pharma Inc. v. Breckenridge Pharm., Inc. 388 F. Supp. 2d 967, 973-74 (E.D. Wis. 2005) (citing Summit Tech, Inc. v. High-Line Med. Instruments, Co., 933 F. Supp. 918, 933 (C.D. Cal. 1996) ("[F]alse statements are actionable under the Lanham Act, even if their truth may be generally within the purview of the FDA."); Ethex Corp. v. First Horizon Pharm. Corp., 228 F. Supp. 2d 1048, 1055 (E.D. Mo. 2002) ("False statements, however, are actionable under the Lanham Act even if they involve FDA-regulated products.")); see also Mutual Pharm. Co., 459 F. Supp. 2d at 934

("[O]nce the FDA has taken a position on a particular matter, courts have consistently allowed the Lanham Act claim to proceed even if in determining the falsity of the alleged representation the court must make reference to the FDA action.").

Several courts have examined the preclusive effect of the FDCA in evaluating claims of equivalence between non-Orange Book drugs and have found that Lanham Act claims are not precluded.[15] See Schwarz Pharma, Inc., 388 F. Supp. 2d at 975 (allowing plaintiff's complaint to proceed "to the extent that it is not seeking the interpretation or direct application of any FDA regulation"); Solvay Pharms., Inc. v. Global Pharms. and Impax Labs., Inc., 298 F. Supp. 2d 880, 884 (D. Minn. 2004) (allowing claims to proceed and noting FDA approval is not required in order to substitute the products or to make an equivalency determination); Pediamed Pharms., Inc., 419 F. Supp. 2d at 725 ("claims of generic or pharmaceutical equivalence [are] not precluded where the drug [is] not listed in the Orange Book and there [is] no indication that FDA approval is needed to make a claim of equivalency"); but see Ethex Corp., 228

[15] As discussed in the Background section above, neither Benziq nor Benprox is listed in the Orange Book.

F. Supp. 2d at 1055 (stating issue "is better left to the FDA" because "this Court would be forced to determine FDA policy in order to determine the truth or falsity of the 'generic' nomenclature").

This Court agrees with the reasoning of those courts that have found that Lanham Act claims of false advertising and unfair competition based on claims of equivalency between non-Orange Book drugs are not precluded by the FDCA. Defendant has not identified any section of the FDCA or its accompanying regulations that this Court would be required to interpret or apply in determining the truthfulness of the claim that Benprox and Benziq are substitutable.

However, in regards to the labeling claims, the FDCA may preclude Lanham Act claims that stray "too close to the exclusive enforcement domain of the FDA." Summit Tech., Inc., 922 F. Supp. at 306; see also Sandoz Pharms., 902 F.2d at 230-31 (not allowing Lanham Act claim that would require court to make a determination as to a label standard on a matter which the FDA has not yet made a finding).[16] The Court will address these labeling issues first, before

[16] The case concerned whether an ingredient on a drug label was properly listed as inactive. The Third Circuit stated:

examining whether there are any material issues of fact pertaining to Benziq's substitution claim.

2. Representations on the Benprox Label

Plaintiffs assert that the representations made by River's Edge on the label of Benprox as to its dosage form, expiration date, and strength are false. Plaintiffs' claim as to misrepresented dosage form is limited to the Benprox gel. Plaintiffs do not claim that Benprox's wash is mislabeled as to its dosage form. Plaintiffs' argument is premised on the fact that the Benprox gel does not meet the FDA definition of a gel because the product separates and runs and behaves more like a lotion than a gel. (Response at 9). However, the USP standard for a benzoyl peroxide gel only requires that the gel be in a suitable gel base.

> The FDA has not found conclusively that demulcents must be labeled as active or inactive ingredients within the meaning of 21 C.F.R. § 210.3(b)(7) . . . . We decline to find and do not believe that the district court had to find . . . that which the FDA, with all of its scientific expertise, has yet to determine. Because "agency decisions are frequently of a discretionary nature or frequently require expertise, the agency should be given the first chance to exercise that discretion or to apply that expertise."

Sandoz Pharms., 922 F.2d at 230-31 (quoting McKart v. United States, 395 U.S. 185, 194, 89 S.Ct. 1657, 23 L.Ed.2d 194 (1969)).

Plaintiffs' expert, Dr. Koepke, acknowledged that the USP are "standards that are uniformly observed throughout the pharmaceutical industry." (SMF at ¶ 70). Plaintiffs have not alleged that the Benprox gel is not in a suitable gel base. Further, Plaintiffs have not established that Benprox must meet the standard set forth in the FDA Data Standards Manual or that meeting the USP standard is insufficient. As noted previously, neither Benziq nor Benprox has been tested or approved by the FDA.

In light of these circumstances, for this Court to determine that there is a material issue of fact as to whether Benprox misrepresents itself as a gel would require this Court to determine that the FDA definition of a gel is the only acceptable standard for a non-FDA approved drug and that the USP standard is unacceptable. Instead of simply applying an FDA decision, this Court would be required to make the decision in the initial instance as to what the appropriate standard is for a non-FDA approved gel. That is a matter on which the FDA, and not this Court, should make the initial determination. See Sandoz, 902 F.2d at 230-31 (not allowing Lanham Act claim that would require court in first instance to interpret label standard). Since this Court is not the appropriate arbiter of what the acceptable standard is, and because Plaintiffs have failed to

show that Benprox does not meet the alternative standard presented by the USP or that the alternative standard is not appropriate, Plaintiffs have not shown that a genuine issue of material fact exists as to whether River's Edge misrepresents its Benprox gel as a gel.

Graceway also claims that River's Edge misrepresents the percentage of benzoyl peroxide contained in the 5.25 percent Benprox wash. Graceway does not argue that the Benprox wash must contain exactly the labeled amount of benzoyl peroxide, but rather that the wash should contain from 90 to 110 percent of the labeled amount. (SMF at ¶ 63). Since five of the ten batches of the wash contained more than 110 percent of the labeled amount of benzoyl peroxide, Plaintiffs argue that the label misrepresented the nature of the Benprox product. (Id. at ¶ 60). However, there are several problems that make it difficult for the Court to accept this argument.

First, the allowable range of benzoyl peroxide that must be present in the wash is the opinion of Dr. Koepke. It is not based on an FDA or USP monograph for a benzoyl peroxide wash, because as Dr. Koepke acknowledges such a monograph establishing the appropriate range does not exist. (Reply at 7). Second, and more importantly, the FDA does not recognize wash as a

dosage form.[17] In order for this Court to accept Dr. Koepke's proffered range of acceptable deviation for benzoyl peroxide in a wash, it must first accept that wash is a valid dosage form. This Court cannot accept that wash is a defined dosage form simply because both Graceway and River's Edge sell products labeled as a wash. To do so would require this Court to define the parameters of what it means to be a wash. This is a task best left to the FDA or the USP.

River's Edge urges this Court to view the Benprox wash as in fact being a gel, since wash is not a defined dosage form and because the Benprox wash is described as an "opaque gel" on the manufacturer's certificates of analysis. If viewed as a gel, all of the batches of Benprox wash fall within the USP established range for benzoyl peroxide gels, not less than 90 percent and not more than 125 percent of the labeled amount of benzoyl peroxide. However, this Court does not need to reach this particular matter in order to resolve the question of whether Plaintiffs' have presented any material issues of fact for trial.

Wash is not an FDA recognized dosage form. No FDA or USP monograph exists that establishes the appropriate range of variation from the

[17] See *supra* note 11.

labeled amount of benzoyl peroxide in a wash. Since wash is not a defined dosage form and because there is no established range of variation for benzoyl peroxide in a benzoyl peroxide wash, there is no genuine issue of fact as to whether the percentage of benzoyl peroxide in Benprox wash products is appropriate. There exists no standard by which this Court or the jury can decide this issue, and it is not appropriate for this Court, as opposed to the FDA or USP, to establish the appropriate standard in the first instance.

Plaintiffs' final label claim is that River's Edge falsely lists a two-year expiration date on the Benprox label. Graceway notes that the percentage of benzoyl peroxide in Benprox failed to meet specifications six months into accelerated testing. (SMF at ¶ 104). Plaintiffs also contend that the two-year expiration date is not warranted because Benprox failed stability testing due to changes in color, viscosity, and gravity. (Id. at ¶¶ 102-03). With regard to the strength of the benzoyl peroxide, Plaintiffs' expert Dr. Koepke agreed that meeting the labeled percentage strength three months into accelerated testing, as Benprox did, was sufficient to warrant a two-year expiration date. (Koepke Depo at 71:17-23). Dr. Koepke also acknowledged that the FDA does not require that viscosity or specific gravity be measured for a topical benzoyl

peroxide product like Benprox. (Id. at 120:14-121:19). Further, in Georgia the standard for substituting one drug for another is pharmaceutical equivalence, which requires the two drugs contain identical amounts of the same active ingredient and be in the same dosage form. O.C.G.A. §§ 26-4-81(a), 26-4-5(27).

Plaintiffs have not demonstrated that color is relevant to dosage form or active ingredient strength, and thus to substitutability, and therefore have not demonstrated the materiality of change in color. Viscosity or specific gravity may be relevant to whether Benprox is properly labeled as a gel or wash. However, Plaintiffs have made no argument that changes in the viscosity or specific gravity affects Benprox's wash products. Also, Plaintiffs have not demonstrated that the USP definition of a benzoyl peroxide gel, as being in a suitable gel base, is not appropriate or that Benprox gels fail to meet this definition. Thus, Plaintiffs have not demonstrated that the changes in viscosity or gravity are material. Finally, Dr. Koepke acknowledges that meeting specifications for benzoyl peroxide strength three months into accelerated testing is sufficient to support a two-year expiration date. Therefore, no

genuine issues of material fact remain as to whether the expiration date listed on Benprox labels is misrepresented or unwarranted.

Finding no genuine issues of material fact as to Plaintiffs claims that River's Edge misrepresents the dosage form, active ingredient strength, or expiration date on the Benprox label, summary judgment is warranted against Plaintiffs as to those claims.

3. Substitution of Benprox for Benziq

Plaintiff's complaint alleges that Defendant falsely promotes Benprox as generically equivalent or otherwise substitutable for Benziq. (Complaint at ¶ 1). As discussed above in Section IA, Plaintiffs' Lanham Act claim that River's Edge falsely advertises Benprox as substitutable for Benziq is not precluded by the FDCA. The two forms of communication that Plaintiffs point to as containing the false or misleading statements of equivalence are the New Product Submission Form and the Kinray flyer. The product submission form identified the active ingredient, dosage form, and strength of available Benprox products. (SMF at ¶¶ 25, 27). This form did not include claims of equivalence to Benziq and did not mention Plaintiffs or Benziq. (SOF at ¶¶ 3-5). The

Kinray flyer on the other hand stated that Benprox "competes with" Benziq. (SMF at ¶¶ 48, 50). The flyer also contained the headline: "Get your money-saving quality River's Edge generic products through Kinray today." (Id. at ¶¶ 48, 49). However, a statement disclaiming the bioequivalence of Benprox was on the email transmittal sheet for the New Product Submissions Form as well as on the face of the Kinray flyer. (SOF at ¶¶ 7, 16). It stated that:

> Even where a River's Edge product is labeled as containing the same active ingredients, they may be subject to differing potency and dissolution specifications and may contain different inactive ingredients. The substitution of prescription pharmaceuticals is governed by state law . . . .

(Id.).

Plaintiffs allege that despite the disclaimer, the headline and the "competes with" language on the flyer was sufficient to portray that Benprox was in fact equivalent to Benziq. Assuming, arguendo, that River's Edge has falsely represented that its product is generic for Benziq, Plaintiffs must also demonstrate that any deception perpetrated by Defendant had a material effect on the purchasing decisions of pharmacies in order to succeed on a Lanham Act false advertising claim. Hickson Corp., 357 F.3d at 1260-61. Plaintiffs have not provided any evidence that the Kinray flyer impacted the decision of

pharmacies to purchase Benprox or of pharmacists to dispense it in the place of Benziq.

In Georgia, the standard for substituting one drug for another is not generic or therapeutic equivalence, but rather pharmaceutical equivalence. O.C.G.A. § 26-4-81(a). Pharmaceutical equivalence only requires that the two drugs be in the same dosage form and contain the same amount of the active ingredient(s).[18] O.C.G.A. § 26-4-5(27). Plaintiffs have not presented any evidence of a genuine issue of material fact that would allow a jury to find that Benprox is not pharmaceutically equivalent to Benziq.[19] Since Plaintiffs have failed to present evidence that Benprox cannot be properly substituted for Benziq in Georgia, there is no evidence that any misrepresentation that may have occurred had a material effect on the decision to substitute Benprox for Benziq. In regards to the New Product Submission form, which listed the active ingredient, strength, and dosage form for Benprox products, Plaintiffs

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[18] The two drugs do not need to contain the same inactive ingredients to be pharmaceutically equivalent.. O.C.G.A. § 26-4-5(27).

[19] See Section IB, *supra* (no genuine issue of material fact exists as to whether River's Edge misrepresented the dosage form, expiration date, or active ingredient strength of its Benprox products).

have failed to present evidence from which a jury could conclude that any of these representations were false.[20]

Plaintiffs assert that River's Edge markets Benprox as substitutable for Benziq without having conducted any comparison testing of the two drugs to determine the accuracy of such a claim. (Response at 13). Whether or not this is true, Defendant does not carry the burden of proving the truthfulness of its statements. It is the Plaintiffs' burden to show that the statements are false or misleading. Plaintiffs have not presented any evidence of comparative testing that demonstrates that Benprox is not equivalent to Benziq in safety or efficacy. Plaintiffs cannot prevail by claiming that the Defendant has failed to disprove their allegations.

Summary judgment is appropriate as to Plaintiffs' Lanham Act claims. Plaintiffs have failed to present evidence by which a jury could find that Defendant either misrepresented Benprox's characteristics on its label or falsely claimed that Benprox was substitutable for Benziq. Therefore Plaintiffs have failed to demonstrate that River's Edge deceived, mislead, or confused

[20] See note 19, *supra*.

consumers. Without such a showing, Plaintiffs cannot prevail under the Lanham Act on either a false advertising or unfair competition claim.

B. Common Law Claims

Plaintiffs also allege as counts three and four of their complaint claims of common law unfair competition and misappropriation. (Complaint at ¶¶ 62-75). The analysis of a Georgia unfair competition claim is co-extensive with the Lanham Act analysis. Optimum Techs., Inc. V. Henkel Consumer Adhesives, Inc., 496 F.3d 1231, 1248 (11th Cir. 2007). Therefore, since Defendant is entitled to summary judgment on the Lanham Act claims, it is also entitled to summary judgment as to the common law unfair competition claim.

Defendant is also entitled to summary judgment on Plaintiffs' common law misappropriation claim. It is likely true that River's Edge gained an "advantage because it was not burdened with the expenses of development and marketing" of Benziq, as Plaintiffs were. (Complaint at ¶ 72). River's Edge's business plan appears to have been to create a drug that could be legally substituted for Benziq, which was already being prescribed by doctors for the treatment of acne. However, even though River's Edge benefitted from

Plaintiffs research and marketing, and even though the company's business plan was likely to do just that, they have not committed any acts for which the law provides a remedy. It is not illegal to copy a product that is unprotected by a patent. See Cooper Indus. v. Leatherman Tool Group, 532 U.S. 424, 441 (2001) ("[C]opying of the functional features of an unpatented product is lawful."). Therefore, Plaintiffs' common law misappropriation claim must fail.

Defendant is entitled to summary judgment as to both of Plaintiffs' common law claims.

II. Defendant's Motion to Compel Discovery [105]

Defendant sought to compel Plaintiffs to respond "completely and appropriately to River's Edge Second Document Requests Numbered 2 through 5." (Defendant's Motion to Compel Discovery [105] at 1). At this time, the outstanding dispute concerns one document. The unresolved conflict concerns drafts of the export report of Mr. Greg Jones, Plaintiffs' damages expert. Defendant claims that Plaintiffs' counsel authored the first draft of Mr. Jones's report and that this draft and any subsequent drafts must be produced in response to the document request. (Id.).

Jones is a vice president of Plaintiff Graceway, and Plaintiffs assert that any drafts of his report that have not been produced are protected by the attorney client privilege. (Plaintiffs' Response to Motion to Compel Discovery [118] at 2). The Court need not decide whether this is the case, because in light of the decision to grant Defendant's Motion for Summary Judgment [129], Defendant's motion is moot. Therefore, Defendant's Motion to Compel Discovery [105] is **DENIED**.

III. Defendant's Emergency Motion to Extend Discovery for Limited Purposes [109] and Motion for Leave to File Amended Motion [181]

Defendant's motion to extend discovery and its subsequent motion for leave to file an amended request to extend discovery are both moot in light of this Court's granting of Defendant's Motion for Summary Judgment [129]. Since the Court has determined that no genuine issue of material fact exists as to any of Plaintiffs' claims against Defendant, there is no need for Defendant to engage in further discovery. Therefore, Defendant's Emergency Motion to Extend Discovery for Limited Purposes [109] as well as Defendant's Motion for Leave to File Amended Motion [181] are **DENIED**.

IV. Plaintiff's Motion for Leave to File a Surreply Brief in Opposition to Defendant's Motion for Summary Judgment [177]

Plaintiffs requested leave to file a surreply brief in opposition to Defendant's motion for summary judgment. Plaintiffs filed a Response to Defendant's Motion for Summary Judgment [142] and Defendant filed a Reply [172]. Neither the Federal Rules of Civil Procedure nor the Local Rules of this Court contemplate the routine filing of briefs following the movant's reply. See Fedrick v. Mercedes-Benz USA, LLC, 366 F. Supp. 2d 1190, 1197 (N.D. Ga. 2005) (declining to permit surreply). "To allow such surreplies as a regular practice would put the court in the position of refereeing an endless volley of briefs." Garrison v. N.E. Ga. Med. Ctr., Inc., 66 F. Supp. 2d 1336, 1340 (N.D. Ga. 1999) (declining to permit surreply).

Plaintiffs' motion is based on two grounds: 1) Defendant raised facts and arguments regarding Plaintiffs' voluntary recall of one lot of Benziq in its reply that were not addressed in its original briefing; and 2) after Plaintiffs' response was filed, the United States Supreme Court issued its opinion in Wyeth v. Levine, 555 U.S. ___, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (March 4, 2009), which Plaintiffs contend is relevant to the summary judgment decision and

warrants briefing. (Plaintiffs' Motion for Leave to File a Surreply Brief ("Pl.'s Motion") [177] at 1-2). While Defendant did discuss a voluntary recall of Benziq in its reply brief, these facts were not relevant to the Court's decision to grant Defendant's Motion for Summary Judgment, and therefore further briefing as to the recall is unwarranted. See First Speciality Ins. Corp. v. 633 Partners, Ltd., 300 Fed. Appx. 777, 788 (11th Cir. 2008) (unpublished) (citing cases of sister circuits in which district court abused its discretion by not allowing a surreply when relying on new evidence presented in the reply brief to grant summary judgment). In its decision to grant Defendant's Motion for Summary Judgment, this Court did not rely upon any evidence or argument to which Plaintiffs have not already had an opportunity to respond. In particular, the Court did not find the discussion of the voluntary recall to be relevant to its decision.

Briefing as to the Supreme Court's Decision in Wyeth v. Levine, 129 S. Ct. 1187, is also unnecessary. Plaintiffs assert that the Supreme Court ruled "that the Food Drug and Cosmetic Act did not preempt state-law tort failure to warn claims even though the claims were based on an FDA approved label." (Pl.'s Motion at 2). In granting Defendant's Motion for Summary Judgment,

this Court did not find that any of Plaintiffs' state law claims were preempted simply because they were based on a drug's label. The Court examined each of the three purported misrepresentations on the Benprox label. (See *supra*, at 22-28.)

Wyeth addressed the question of whether FDA approval of a drug's label provided a complete defense to a state-law tort claim for failure to warn. 129 S.Ct. at 1191. The defendant in that case argued that state law could not create a stricter labeling standard than that required by the FDA. That is not the question in the present case. The present labeling issues concern whether River's Edge misrepresented the strength, dosage form, and/or expiration date on the Benprox label. Plaintiffs have failed to identify any state that establishes standards in regards to these three items specifically. The relevant state-law tort claims, like the federal causes of action, turn on whether Defendant made misrepresentations on Benprox's label. The Court found that the expiration date was not a misrepresentation. (See *supra*, at 28.) In regards to the dosage form and active ingredient claims, the Court did not decline to address the issue because state law interfered with federal law, but rather because deciding whether the labeled dosage form or active ingredient strength were

misrepresentations would require the Court to make decisions of a scientific or regulatory manner that are best left to the FDA in the first instance. (See *supra*, at 22-26.)

Since the recall of Benziq discussed in Defendant's reply brief and the decision in Wyeth v. Levine, 129 S. Ct. 1187, are not relevant to this Court's grant of summary judgment, a surreply brief is not warranted. Therefore, Plaintiff's Motion for Leave to File a Surreply Brief in Opposition to Defendant's Motion for Summary Judgment [177] is **DENIED**.

V. Conclusion

For the foregoing reasons, Defendant's Motion for Summary Judgment [129] is **GRANTED**, and Defendant's Motion to Compel Discovery [105], Defendant's Emergency Motion to Extend Discovery for Limited Purposes [109], Defendant's Motion for Leave to File Amended Motion [181], and Plaintiff's Motion for Leave to File a Surreply Brief in Opposition to Defendant's Motion for Summary Judgment [177] are **DENIED**.

SO ORDERED this 6th day of November, 2009.

RICHARD W. STORY
UNITED STATES DISTRICT JUDGE