UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Solvay Pharmaceuticals, Inc.,

Plaintiff,

v.

Ethex Corporation and
KV Pharmaceutical Company,

Defendants.

Civil No. 03-2836 (JRT/FLN)

REPORT AND RECOMMENDATION

Saul Perloff, for Plaintiff.
Thomas Morrison, for Defendants.

THIS MATTER came before the undersigned United States Magistrate Judge on February 17, 2006, on Defendants' Motion for Partial Summary Judgment [#72]. The matter was referred to the undersigned for Report and Recommendation pursuant to 28 U.S.C. § 636 and Local Rule 72.1. For the reasons that follow, this Court recommends Defendants' Motion be granted in part.

I. BACKGROUND

Defendant KV Pharmaceutical Company manufactures, and Defendant Ethex Corporation markets, the Pangestyme family of pancreatic enzymes. Pancreatic enzymes are used by patients who have a shortage of natural digestive enzymes, such as people suffering from pancreatitis or cystic fibrosis. Plaintiff Solvay Pharmaceuticals, Inc., produces Creon, a competing pancreatic enzyme. Defendants describe Pangestyme as a "branded generic" that they promote as a lower-priced alternative to Creon. See Def. Mem. p. 1.

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A. FDA Framework

Prescription pancreatic enzyme supplements are subject to FDA regulation. See Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301-92 (1982). The FDCA requires FDA approval, through a "new drug application" ("NDA") before a new drug may be put on the market. Id. at §§ 331(d), 355(a). A product similar to an NDA-approved drug may be approved and marketed based on an "abbreviated new drug application" ("ANDA"). Id. at § 355(j). An ANDA requires the manufacturer of the similar drug to demonstrate that the two drugs are therapeutically equivalent – that is, pharmaceutically equivalent and bioequivalent.[1] Id. at § 355(j)(2)(A)(i)-(viii).

In 1995, the FDA declared that all pancreatic enzyme drugs would require NDA or ANDA approval beginning in April 2008, but permitted such drugs to remain on the market during the approval process. See 69 Fed. Reg. 23410 (Apr. 28, 2004). Thus, neither Creon nor Pangestyme has been tested, approved, or compared by the FDA.

B. Complaint and Procedural History

Plaintiff brought the instant suit in April 2003, alleging inter alia that Defendants' advertising of Pangestyme is false and misleading under the Lanham Act and Minnesota state law. Plaintiff alleges that Defendants falsely advertise Pangestyme as a "generic equivalent" that is "pharmaceutically equivalent," bioequivalent" and "therepeutically equivalent" to Creon. See Complaint ¶¶ 28-34. Plaintiff alleged seven causes of action in the Complaint: (1) false advertising in violation of § 43(a) of the Lanham Act; (2) unfair competition in violation of § 43(a) of the Lanham Act; (3) violation of the Minnesota Unfair Trade Practices Act, Minn. Stat. § 325D.13; (4)

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[1] "Pharmaceutically equivalent" means the two drugs share the same active ingredients, strength and dosage. See 21 C.F.R. § 320.1(c). "Bioequivalent" means the two drugs do not have significantly different rates and extent of absorption in the body. See Id.

violation of the Minnesota Uniform Deceptive Trade Practices Act, Minn. Stat. § 325D.44; (5) violation of the Minnesota False Advertising Act, Minn. Stat. § 325F.67; (6) violation of the Minnesota Consumer Fraud Act, Minn. Stat. § 325F.69; and (7) a request for declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202 that Pangestyme CN-10 and CN-20 may not be lawfully substituted for Creon.

In July 2003, Defendants moved for Judgment on the Pleadings. In the motion, Defendants sought to dismiss Plaintiff's request for declaratory relief that Pangestyme could not be substituted for Creon under the various state laws governing substitution (Count 7).

In an Opinion and Order dated March 30, 2004 [#39], the Honorable Judge Tunheim dismissed Plaintiff's request for a declaratory judgment that Pangestyme could not be substituted for Creon. The Court found that the requested relief would affect individual pharmacists and pharmacist boards who were not parties to the case, and further, that the requested injunction would conflict with the laws of states permitting substitution based on independent judgments of therapeutic or pharmaceutical equivalence. See Order [#39] p. 12. Finally, the Court reasoned that Plaintiff would still be able to obtain the relief it seeks despite the dismissal of their prayer for declaratory relief. The Court explicitly stated that if Plaintiff is able to ultimately prove "that Pangestyme and Creon are not, in fact, 'generic,' 'comparable,' 'substitutable' or 'equivalent,' [Defendants will] not be able to market Pangestyme as any of those things." See Order [#39] pp. 12-13.

C. Discovery

According to Defendants, a core issue in this case is whether their advertising for Pangestyme conveys the message that Pangestyme is bioequivalent and therapeutically equivalent

to Creon within the meaning of the FDA's regulations for ANDA drugs. On November 30, 2004, Defendants served Plaintiff with Interrogatories asking Plaintiff to identify each advertisement or promotion that contains false or misleading representations. In Answers provided on December 30, 2004, Plaintiff identified nine allegedly false advertising claims for Pangestyme, six of which are at issue in the instant motion: 1) that Pangestyme "meets USP standards"; 2) that Pangestyme "is high quality"; 3) that Pangestyme is "safer or more effective" than Creon; 4) that Pangestyme is "safer or more effective" than other enzymes because its enteric coating does not utilize acetone; 5) that Pangestyme is "safer or more effective" than other enzymes because it is made in the United States; and 6) that Pangestyme is "endorsed or approved" by the Cystic Fibrosis Foundation ("CFF").

D. The Instant Motion

Defendants move for partial summary judgment, seeking to dismiss: 1) the six alleged performance claims identified in Plaintiff's interrogatory answers (the "unpled claims"); 2) the claim that Defendants violate the Lanham Act because Pangestyme is not substitutable for Creon; and 3) the claim that Defendants violate the Lanham Act because they market Pangestyme as an "alternative" to Creon and invite customers to compare Pangestyme to Creon.

II. LEGAL ANALYSIS

A. Standard of Review

The Supreme Court has held that summary judgment is to be used as a tool to isolate and dispose of claims or defenses that are either factually unsupported or based on undisputed facts. See Celotex Corp. v. Catrett, 477 U.S. 317, 323-27 (1986). Therefore, summary judgment is appropriate when the moving party establishes that there is no genuine issue as to any material fact and the

moving party is entitled to judgment as a matter of law. See Fed. R. Civ. P. 56(c); Celotex, 477 U.S. at 322-23. For these purposes, a disputed fact is "material" if it must inevitably be resolved and the resolution will determine the outcome of the case; while a dispute is "genuine" if the evidence is such that a reasonable jury could return a verdict for the non-moving party. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

When considering a motion for summary judgment, a court should construe all evidence in favor of the non-moving party. Id. at 255. Thus, summary judgment is appropriate when the court has viewed the facts and the inferences drawn from those facts, in a light most favorable to the non-moving party, and found no triable issue. See Southwall Technologies, Inc. v. Cardinal IG Co., 54 F.3d 1570, 1575 (Fed. Cir. 1995).

B. The Lanham Act

The Lanham Act provides a civil remedy for a plaintiff who is injured by a defendant's false or deceptive advertising. See 15 U.S.C. § 1124(a)(1). To prevail on a claim under the Lanham Act, a plaintiff must establish that: 1) the defendant made false statements of fact about its own products, or the plaintiff's products, in an advertisement; 2) the advertising actually deceived or tended to deceive a substantial segment of its audience; 3) the deception is material because it is likely to influence buying decisions; 4) the defendant caused falsely advertised goods to enter interstate commerce; and 5) that the plaintiff was injured or is likely to be injured as a result. Lenscrafters, Inc. v. Vision World, 943 F.Supp. 1481, 1488 (D. Minn. 1996) citing Alternative Pioneering v. Direct Innovative Products, 822 F.Supp. 1437, 1441-42 (D. Minn. 1993). False statements are actionable under the Lanham Act, even if their truth may be generally within the purview of the FDA. Schwrtz Pharma, Inc. v. Breckenridge Pharmaceutical, Inc., 388 F. Supp.2d 967, 974 (E.D.

Wis. 2005) citing Ethex Corp. v. First Horizon Pharmaceutical Corp., 228 F.Supp.2d 1048, 1055 (E.D. Mo. 2002).

The plaintiff can satisfy its burden as to the first factor by demonstrating that the defendant made statements of fact regarding its own products, or the plaintiff's products, which are either literally false, or are literally true but likely to mislead customers. Lenscrafters, 943 F. Supp. at 1488 citing Alternative Pioneering, 822 F.Supp. at 1442; Johnson & Johnson-Merck v. Rhone-Poulenc Rorer, 19 F.3d 125, 129 (3rd Cir. 1994). To determine whether a particular representation is literally false, it must be analyzed with its full context. United Industries Corp. v. Clorox Co., 140 F.3d 1175, 1180 (8th Cir. 1998). Whether an advertisement is literally false presents a question of fact. Lenscafters, 943 F. Supp. at 1488, citing Johnson & Johnson v. GAC Int'l. Inc., 862 F.2d 975, 979 (2nd Cir. 1988). When advertising is alleged to be literally true yet misleading, the challenging party bears the burden of proving actual deception by a preponderance of the evidence; the challenging party must show how consumers actually react. Id. at 1488-89, citing Sandoz Pharmaceuticals v. Richardson-Vicks, Inc., 902 F.2d 222, 228-229 (3rd Cir. 1990). The challenging party satisfies its burden by producing evidence of actual consumer reaction to the challenged advertising, which can take the form of circumstantial evidence, such as consumer surveys, consumer reaction tests or market research. Id. at 1489, citing Ortho Pharmaceutical Corp. v. Cosprophar, Inc., 32 F.3d 690, 695 (2nd Cir. 1994).

C. The Unpled Claims

1. Plaintiff Has Satisfied Rule 8

Defendants move to dismiss Plaintiff's claims of false advertising identified in the answers to interrogatories provided on December 30, 2004. Defendants first argue that the six claims should

be dismissed because they were never set forth in a pleading. The Court disagrees and finds that Plaintiff satisfied the notice pleading requirements of the Federal Rules of Civil Procedure. All the Rules require is that a complaint give the parties "fair notice of the nature and basis or grounds for a claim, and a general indication of the type of litigation involved." Redland v. Ins. Co. v. Shelter Gen. Ins. Co., 121 F.3d 443, 446 (8th Cir. 1997). Plaintiff's Lanham Act count alleges that "Defendants' advertisements are literally and/or impliedly false and misleading and in direct violation of Section 43 of the Lanham Act." The Complaint provided Defendants adequate notice of the nature of Plaintiff's claims. The allegations of false advertising identified in Plaintiff's discovery responses in December 2004 relate to the Complaint's assertions that Defendants make false statements in their marketing of Pangestyme. The specific instances of false advertising Plaintiff identified during discovery fit within the ambit of the Complaint, and should not be dismissed for Plaintiff's failure to comply with the notice requirements under Rule 8 of the Federal Rules of Civil Procedure.

2. "High Quality"

Some of the claims of false advertising should be dismissed, however, because Defendants never made the claims alleged to be false, and because one claim is unactionable. Plaintiff asserts that Defendants have unlawfully advertised that Pangestyme is "high quality." The statement that Pangestyme is of "high quality," however, constitutes non-actionable puffery. A claim that consists merely of broad, vague and commendatory language is regarded as non-actionable puffing. See American Italian Pasta Co. v. New World Pasta Co., 371 F.3d 387, 391 (8th Cir. 2004) ("if the statement is not specific and measurable, and cannot be reasonably interpreted as providing a benchmark by which the veracity of the statement can be ascertained, the statement constitutes

puffery"); Lenscrafters, 943 F. Supp. at 1498 (characterizing claim that defendant employed "the most advanced equipment available" as no more than generalized exaggeration expressed in broad, vague and commendatory terms that constituted unactionable touting). Despite Plaintiff's arguments, the Court fails to see how the doctrine of puffery should apply differently to the marketing of prescription drugs. See Ethex Corp. v. First Horizon Pharm. Corp., 228 F. Supp. 2d at 1057 (dismissing Lanham Act counterclaims based on statements extolling the virtues of plaintiff's prescription pre-natal vitamins because the statements were mere puffery). Because Defendants' alleged advertising of Pangestyme as "high quality" constitutes unactionable puffery, Plaintiff's claim that such statement violates the Lanham Act should be dismissed.

3. "Safer and More Effective" and "Endorsed by the CFF"

Four of the claims identified in Plaintiff's interrogatory answers should be dismissed because Defendants represent they have never made those statements. In its answers, Plaintiff claimed that Defendants made the following claims, which Plaintiff alleged are violative of the Lanham Act: that Pangestyme is "safer or more effective than Creon;" that Pangestyme is "safer or more effective" than competing enzymes because its enteric coating does not utilize acetone or other organic solvents; that Pangestyme is "safer or more effective" than competing pancreatic enzymes because it is made in the United States; and that Pangestyme is endorsed or approved by the Cystic Fibrosis Foundation ("CFF"). Defendants represent that it has never made these claims in its advertising. They represent that they have never touted Pangestyme as being safer or more effective than Creon. Though Defendants have stated that Pangestyme is the only pancreatic enzyme manufactured, packaged and inspected in the United States, Defendants have never claimed that this rendered Creon less effective than Pangestyme. Likewise, Defendants have never advertised that

Pangestyme's enteric coating made without acetone makes Pangestyme safer or more effective than Creon. Neither have Defendants advertised that Pangestyme is endorsed by the CFF. Because these claims have never appeared in Defendants' advertising, they should be dismissed.

4. "Meets USP Standards"

Insofar as Defendants seek to dismiss Plaintiff's allegation that Defendants' advertisement that Pangestyme "meets USP standards" violates the Lanham Act, the motion should be denied. At the hearing, Defendants admit that they included this claim in their advertising. As such, it is a question of fact whether the statement is false or misleading. Summary judgment should be denied as to this allegation.

D. The Substitutability Claim

According to Defendants, Plaintiff claims in its interrogatory answers that Defendants falsely promote Pangestyme as being "substitutable" or a "generic substitute" for Creon. Defendants argue that the substitutability claim should be dismissed because the claim is merely a restatement of the declaratory judgment claim as a false advertising claim, and because Defendants do not promote Pangestyme as being automatically substitutable for Creon. See Def. Mem. p. 13.

1. The Substitutability Claim Is Not Foreclosed by the Court's Previous Order

In the Order dated March 30, 2004, Judge Tunheim noted that whether a drug may be lawfully substituted for another depends upon the pharmacy laws of the fifty states. In dismissing Plaintiff's claim for a declaratory judgment, the court reasoned that if the requested injunction issued, and Defendants were enjoined from marketing Pangestyme to encourage pharmacists to believe that Pangestyme and Creon are essentially interchangeable, individual pharmacists could be held responsible for the wrongful substitution. The Court therefore dismissed the claim because

courts are not empowered to issue relief against persons who would be affected by the relief but who are not parties to the case. See Order. p. 12.

The Court continued that if Plaintiff is ultimately able to prove that Pangestyme and Creon are not in fact substitutable, Defendants would not be able to market Pangestyme as substitutable. See Order pp. 12-13. In other words, the Court did nothing more than dismiss Plaintiff's claim for declaratory relief; it did not foreclose Plaintiff's claim that Defendants falsely market Pangestyme as substitutable for Creon in violation of the Lanham Act. See Mille Lacs Band of Chippewa Indians v. State of Minnesota, 952 F. Supp. 1362, 1371 (D. Minn. 1997) (controversy suitable to declaratory relief must be appropriate for judicial determination; must be real and substantial controversy admitting of specific relief through a decree of conclusive character) (quotation omitted); United States v. State of Washington, 759 F.2d 1353, 1356 (9th Cir. 1985) (decision to grant declaratory relief is left within the sound discretion of the trial court, even where there is a justiciable controversy). Though the Court found declaratory relief inappropriate, it opined that Plaintiff could pursue the same relief under its Lanham Act allegations. The Court specifically noted that if Plaintiff is able to articulate concrete facts that demonstrate that Pangestyme is not substitutable, Defendants would not be able to market Pangestyme as substitutable.

Though the determination of substitutability may require analysis of circumstances that arise under fifty state laws, as Defendants argue, the complexity of the claim does not give the Court reason to dismiss it. Plaintiff may pursue its claim that Defendants falsely advertise Pangestyme as substitutable for Creon.

2. Issue of Fact Whether Advertising Falsely Promotes Pangestyme as Substitutable or Misleads Customers Into Believing Pangestyme Is Substitutable

Alternatively, Defendants argue that the substitutability claim should be dismissed because they have never promoted Pangestyme as a generic substitute that is interchangeable with Creon. Defendants argue that they have only advertised Pangestyme as a branded generic that is available for substitution where substitution is appropriate. See Def. Mem. p. 16. Plaintiff asserts that Defendants "actively" encourage the substitution of Pangestyme for Creon. Plaintiff argues that though Defendants' promotions may not use the word "substitute," they intend to promote and encourage substitution through such phrases as "invitation to compare." See Pl. Mem. p. 19.

To prevail on their Lanham Act claim, Plaintiff must show that Defendants' advertising and use of the terms "invitation to compare" or "available for substitution" either falsely portrays Pangestyme as a substitute for Creon, or misleads customers into believing Pangestyme is substitutable. See Lenscrafters, 943 F. Supp. at 1488. A genuine issue of material fact has been raised and Plaintiff is entitled to present the jury with direct and circumstantial evidence whether Defendants' advertising falsely claimed or implied that Pangestyme is substitutable for Creon.

E. "Alternative to" Claim

Lastly, Defendants move to dismiss Plaintiff's allegation that Defendants unlawfully promote Pangestyme as an "alternative" to Creon and unlawfully invite its customers to "compare" Pangestyme to Creon. Defendants admit that they identify Pangestyme as an "alternative" to Creon, and that they invite customers to "compare" it to branded products. See Def. Mem. p. 19. Defendants argue that the Lanham Act cannot be read to prevent an advertiser from referring to its product as an "alternative" to a competitor's product, or to prevent an advertiser from inviting its customers to "compare" products. The Court agrees.

Defendants concede that a manufacturer of a branded drug may challenge a generic

competitor who makes an express, but false, claim of bioequivalence. See Def. Mem. p. 24. Defendants argue that while a manufacturer of a branded drug is entitled to invoke the Lanham Act against a manufacturer of a lower-priced alternative if the alternative makes a specific false claim, e.g., where the defendant's product falsely advertises that it is approved for the same indications as plaintiff's, or that it is bioequivalent to the plaintiff's product, a manufacturer may not prevent a defendant from promoting its product as an "alternative" to the branded product, or from inviting customers to "compare" the products.[2]

Plaintiff argues that Defendants' use of the term "alternative" in the context of prescription drugs means "generic alternative," and that "generic alternative" in turn means "pharmaceutically equivalent." See Pl. Mem. pp. 22-23. The Court refuses to make this leap. First, no federal statute or FDA regulation has defined the term "generic." Ethex Corp. v. First Horizon Pharm. Corp., 228 F. Supp. 2d at 1055; but see Healthpoint, Ltd. v. Ethex Corp., 273 F.Supp.2d 817, 866-67 (W.D.Tex.,2001) citing FDA amicus brief ("the FDA has an interest in insuring that only one definition of FDA terms of art, such as 'therapeutically equivalent' and 'generic,' is used in the context of drug approval, acceptance and use").

Secondly, the Court concludes that Pangestyme, a non-FDA-approved drug, can identify itself as an "alternative" or comparative product to Creon without being bioequivalent to Creon. See Florida Breckenridge, Inc. v. Solvay Pharmaceuticals, Inc., 1998 U.S. Dist. LEXIS 14742 (S.D.Fla. March 18, 1998) (holding that as a matter of law, a claim of generic equivalence is not a claim of bioequivalence or therapeutic equivalence); Ethex Corp. v. First Horizon Pharm. Corp., 228 F. Supp.

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[2] Defendants do not move to dismiss, in the instant motion, Plaintiff's allegation that Defendants' advertising communicates that Pangestyme is bioequivalent and therapeutically equivalent to Creon within the meaning of the FDA regulations. See Def. Mem. p. 6.

2d at 1055 (holding that in the case of non-FDA-approved drugs, a generic manufacturer is entitled to position its product as an alternative to the branded drug without being held to the bioequivalence and therapeutic equivalence standard applicable to FDA-approved drugs) ("this type of claim is better left to the FDA who has the expertise in enforcing and interpreting its own complicated regulations...especially...where the FDA has not required the [product] to meet any standards"). The mere marketing of a generic alternative does not carry an implication that the generic is bioequivalent and therapeutically equivalent to the branded drug within the meaning of the FDA. To the extent Plaintiff claims a violation of the Lanham Act based on Defendants' marketing of Pangestyme as an "alternative" or comparable to Creon, the claim should be dismissed.

III. RECOMMENDATION

Based upon the files, records and proceedings herein, **IT IS HEREBY RECOMMENDED** that Defendants' Motion for Partial Summary Judgment [#72] be **GRANTED in part** and **DENIED in part,** as follows:

A) Insofar as Defendants move to dismiss Plaintiff's allegations that Defendants violate the Lanham Act by advertising that Pangestyme is "high quality," "safer or more effective than Creon," "safer or more effective than" competing enzymes because of its enteric coating, "safer or more effective than" competing enzymes because it is made in the United States, and that Pangestyme is endorsed or approved by the CFF, the Motion should be **GRANTED**. Insofar as Defendants move to dismiss the allegation that they violated the Lanham Act by advertising that Pangestyme "meets USP standards," the Motion should be **DENIED**.

B) Insofar as Defendants move to dismiss the allegation that they violate the Lanham Act by falsely promoting Pangestyme as "substitutable" for Creon, the Motion should be **DENIED**.

C) Insofar as Defendants move to dismiss the allegation that they violate the Lanham Act by advertising Pangestyme as an "alternative" to Creon, or by inviting customers to "compare" Pangestyme to Creon, the Motion should be **GRANTED**.

DATED: February 22, 2006

s/ *Franklin L. noel*
FRANKLIN L. NOEL
United States Magistrate Judge

Pursuant to the Local Rules, any party may object to this Report and Recommendation by filing with the Clerk of Court and serving on all parties, on or before **March 10, 2006**, written objections which specifically identify the portions of the proposed findings or recommendations to which objection is being made, and a brief in support thereof. A party may respond to the objecting party's brief within ten days after service thereof. All briefs filed under the rules shall be limited to 3500 words. A judge shall make a de novo determination of those portions to which objection is made.

Unless the parties are prepared to stipulate that the District Court is not required by 28 U.S.C. § 636 to review a transcript of the hearing in order to resolve all objections made to this Report and Recommendation, the party making the objections shall timely order and cause to be filed by **March 10, 2006,** a complete transcript of the hearing.

This Report and Recommendation does not constitute an order or judgment of the District Court, and it is, therefore, not appealable to the Circuit Court of Appeals.