UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

SCHERING-PLOUGH HEALTHCARE PRODUCTS, INC.,

Plaintiff,

v. Case No. 07-CV-642

SCHWARZ PHARMA, INC.,
KREMERS URBAN, LLC,
BRECKENRIDGE PHARMACEUTICALS, INC.,
PADDOCK LABORATORIES, INC.,

Defendants.

ORDER

Plaintiff Schering-Plough HealthCare Products, Inc. ("Schering-Plough") filed its complaint on July 12, 2007, alleging claims brought pursuant to Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B) and Wisconsin state law against defendants Schwarz Pharma Manufacturing, Inc. ("Schwarz"), Kremers Urban, LLC, Breckenridge Pharmaceutical, Inc., and Paddock Laboratories, Inc. Schering-Plough claims that the defendants made false and misleading statements in connection with the marketing and sale of Polyethylene Glycol 3350 Powder for Oral Solution laxative drugs ("Polyethylene Glycol 3350"). On August 13, 2007, Schering-Plough moved for partial summary judgment as to liability on its claim of false advertising in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a). The defendants have filed separate motions to dismiss. For the reasons set forth below, the court will deny Schering-Plough's motion for partial summary judgment and grant the defendants' motions to dismiss this action.

BACKGROUND

The material facts are not in dispute. All the parties in this action market drugs approved by the United States Food and Drug Administration ("FDA") pursuant to a comprehensive drug approval and regulatory scheme under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-399. Under the FDCA, a "new drug" cannot be sold unless it is first approved by the FDA. *See* 21 U.S.C. § 355(a). Approval is obtained either through a New Drug Application ("NDA"), *see* 21 U.S.C. § 355(b), 21 C.F.R. § 314.50, or an Abbreviated New Drug Application ("ANDA"). A product similar to an NDA approved drug may be approved and marketed based on an ANDA. *See* 21 U.S.C. § 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. *Id.* at § 355(j)(2)(A)(i)-(viii). An ANDA also requires the manufacturer of the similar drug to demonstrate that the "labeling proposed for the new drug is the same as the labeling approved for the listed drug . . . ." *Id.* at § 355(j)(2)(A)(v).

On February 18, 1999, the FDA approved Braintree Laboratories, Inc.'s ("Braintree") NDA to market Polyethylene Glycol 3350 as a prescription-only drug under 21 U.S.C. § 355(b). (O'Mullane Decl. ¶¶ 7-8.) On October 6, 2006, the FDA approved Braintree's NDA to market Polyethylene Glycol 3350 as an over-the-counter drug. (*Id*. at ¶ 12.) The FDA also granted Braintree three-year exclusivity to market Polyethylene Glycol 3350 as an over-the-counter drug, beginning October 6, 2006. (*Id*. at ¶ 13.) In August 2006, Braintree granted Schering-Plough an

exclusive right to market over-the-counter Polyethylene Glycol 3350, and on February 19, 2007, Schering Plough began marketing its Polyethylene Glycol 3350 over-the-counter product, MiraLAX. (*Id*. at ¶ 14.) The polyethylene glycol 3350 molecule is the only ingredient in each of the parties' Polyethylene Glycol 3350 products; there are no inactive ingredients. (*Id*. at ¶ 15.)

Between 2004 and 2006, the defendants filed ANDA's in order to obtain FDA approval to market generic equivalent Polyethylene Glycol 3350. These ANDA's were based upon the approved NDA filed by Braintree which allowed for the marketing of Polyethylene Glycol 3350 as a prescription-only drug. (Compl. ¶¶ 18-21.) Before the FDA approved Braintree's NDA to market Polyethylene Glycol 3350 as an over-the-counter drug, the FDA approved the defendants' ANDA's, permitting the defendants to market Polyethylene Glycol 3350 as a prescription-only drug. (*Id*.) Because the FDA granted Braintree three-year exclusivity to market Polyethylene Glycol 3350 as an over-the-counter drug, the FDA currently cannot approve any ANDA's for over-the-counter Polyethylene Glycol 3350.

After the defendants' ANDA's were approved, the defendants began marketing and selling their Polyethylene Glycol 3350 products as "Rx only" or "prescription only" laxatives. (Howard Decl. ¶¶ 12-20, Exs. 1-8.) Schering-Plough asserts that the defendants' use of these "prescription only" statements on their labels constitutes false advertising in violation of the Lanham Act because Polyethylene Glycol 3350 is available from Schering-Plough without a prescription. The defendants contend that because their ANDA's were based upon the approved

NDA which allowed for the marketing of Polyethylene Glycol 3350 as a "prescription only" drug, their products' labels are required by the FDA and FDCA to indicate that the products are available only by prescription.

ANALYSIS

Because the court is able to rule on Schering-Plough's motion for partial summary judgment without the need to preemptively interpret and enforce FDA regulations, the court will address that motion first. Summary judgment is appropriate where the moving party establishes that there is no genuine issue of material fact and that the party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). "Material facts" are those facts which "might affect the outcome of the suit," and a dispute about a material fact is "genuine" if a reasonable finder of fact could find in favor of the nonmoving party. *See Anderson v. Liberty Lobby*, *Inc.*, 477 U.S. 242, 248 (1986). Summary judgment is appropriate where a party has failed to make "a showing sufficient to establish the existence of an element essential to that party's case and on which the party will bear the burden of proof at trial." *Celotex*, 477 U.S. at 322-23. A party opposing summary judgment may not rest upon the mere allegations or denials of the adverse party's pleading, but must set forth specific facts showing that there is a genuine issue for trial. Fed. R. Civ. P. 56(e). In determining whether a genuine issue of material fact exists, the court construes all facts and reasonable inferences in a light most favorable to the non-moving party. *Anderson*, 477 U.S. at 255.

Section 43(a)(2) of the Lanham Act "prohibits the use of false or misleading statements or representations of fact in commercial advertising, and establishes a private remedy for any violation thereof." *Abbott Labs v. Mead Johnson & Co.*, 971 F.2d 6, 13 (7th Cir.1992). A false statement that constitutes a violation of the Act "generally falls into one of two categories: (1) commercial claims that are literally false as a factual matter; or (2) claims that may be literally true or ambiguous, but which implicitly convey a false impression, are misleading in context, or likely to deceive consumers." *Hot Wax, Inc. v. Turtle Wax, Inc.*, 191 F.3d 813, 820 (7th Cir. 1999). "When the statement in question is actually false, the plaintiff need not show that the statement either actually deceived customers or was likely to do so." *Id.*

Here, it is undisputed that Polyethylene Glycol 3350 is available from Schering-Plough without a prescription, but is only available from the defendants with a prescription. Schering-Plough asserts that the defendants' commercial use of the statements "Rx only" and "a prescription only laxative" on their labels constitutes literally false statements, and as a result, no other evidence is necessary to prove their false advertising claim. Therefore, Schering-Plough argues, the undisputed facts demonstrate that the defendants made literally false statements in their commercial interstate advertising, and, thus, Schering-Plough is entitled to summary judgment on its claims that the defendants violated Section 43(a) of the Lanham Act.

In reviewing allegedly false and misleading statements, courts are to read the statements in their entirety and in context to determine whether they are actionable.

See, e.g., Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1139 (9th Cir. 1997) ("When evaluating whether an advertising claim is literally false, the claim must always be analyzed in its full context."); *Castrol, Inc. v. Pennzoil Co.*, 987 F.2d 939, 946 (3rd Cir. 1993) ("in assessing whether an advertisement is literally false, a court must analyze the message conveyed in full context."); *Schwarz Pharma, Inc. v. Breckenridge Pharm., Inc.*, 388 F. Supp. 2d 967, 976 (E.D. Wis. 2005) ("To determine whether a particular representation is literally false, it must be analyzed with its full context."). In addition, the specific audience is part of the context that must be considered in deciding whether a statement is literally false. "[C]ontext can often be important in discerning the message conveyed and this is particularly true where, as here, the target of the advertising is not the consuming public but a more well informed and sophisticated audience." *Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 229 (3d Cir. 1990) (citation and internal quotation marks omitted).

Schering-Plough argues that according to the "Rx only" and "prescription only" statements on the defendants' products' labels, the defendants communicate the false message that *all* Polyethylene Glycol 3350 is only available with a prescription. However, the defendants' use of the "Rx only" and "prescription only" statements must be considered in the context of the full bottle label. *See Schwarz Pharma, Inc.*, 388 F. Supp. 2d at 976. The context of the defendants' product label is particularly relevant here because the target audience for the defendants' products predominantly consists of licensed pharmacists, buyers who are trained as

pharmacists, and other individuals with significant experience in the pharmaceutical industry. (Lapila Decl. ¶ 2.) Analyzing the "Rx only" and "prescription only" statements on the defendants' products' labels in their full context, a reasonable finder of fact could reasonably conclude that the statements only refer to the specific products on which the statements appear. Indeed, the defendants' products' labels contain unique trade names, manufacturer names, and logos. Each of the defendants' products' labels also contains a unique National Drug Code ("NDC") that identifies the manufacturer of each product, the specific product, and the packaging type. *See* 21 C.F.R. § 207.35(b). In addition, given that pharmacists who purchase the defendants' products have "special knowledge of a class of products," it is less likely that the defendants' use of the statements "Rx only" and "prescription only" would be interpreted to convey the message that all Polyethylene Glycol 3350 products are only available with a prescription. *See Sandoz*, 902 F.2d at 229-30. Thus, viewing the facts in the light most favorable to the defendants, as the court must, a reasonable finder of fact could conclude that the "Rx only" and "prescription only" statements refer to the specific products on which they appear. And given that Polyethylene Glycol 3350 is available from the defendants on a prescription only basis, a reasonable finder of fact could conclude that these statements are not literally false. Furthermore, Schering-Plough does not allege that the statements are ambiguous or literally true, and Schering-Plough has not presented evidence of actual consumer confusion to suggest that the statements are misleading in context. *See, e.g., Sanfield, Inc. v. Finlay Fine Jewelry Corp.*, 168 F.3d 967, 971-72 (7th Cir.

1999) ("where the statement is literally true or ambiguous, then the plaintiff is obliged to prove that the statement is misleading in context, as demonstrated by actual consumer confusion."). In light of the foregoing, the court is obliged to deny Schering-Plough's motion for partial summary judgment.

Turning now to the defendants' motions to dismiss, they assert that Schering-Plough's Lanham Act claim should be dismissed because the claim requires the court to interpret and apply the FDCA before the FDA has had a chance to do so. Enforcement of the FDCA is permitted exclusively "by and in the name of the United States" or, in certain circumstances, by a state. 21 U.S.C. § 337. Courts have held that it is not proper "for a court in a Lanham Act case to determine preemptively how a federal administrative agency will interpret and enforce its own regulations." *Sandoz*, 902 F.2d at 231. This is both because such intervention by a court would be tantamount to allowing a private right of action under the FDCA, which the statute does not permit, *id.*, and because it would violate the directive of the Supreme Court that "[b]ecause '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.'" *Id.* (quoting *McKart v. United States*, 395 U.S. 185, 194 (1969)).

When and if a false advertising claim strays "too close to the exclusive enforcement domain of the FDA," it cannot stand. *Schwarz Pharma, Inc.*, 388 F. Supp. 2d at 974 (quoting *Summit Tech. v. High-Line Medical Instruments Co.*, 922 F. Supp. 299, 306 (C.D. Cal. 1996). Such claims would "allow a private litigant to

interfere with the FDA's own investigatory time-table and prosecutorial decision-making." *Id.* However, courts have also held that false statements are actionable under the Lanham Act, even if their truth may be generally within the purview of the FDA. *See, e.g., Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1138 (4th Cir. 1993).

Here, the defendants assert that the plaintiff's Lanham Act claim should be dismissed because the issue of whether the defendants' products are mislabeled under FDA standards is an issue within the exclusive purview of the FDCA, and thus not properly decided in a Lanham Act case. Pursuant to the FDCA, an ANDA applicant is required "to show that the labeling proposed for the [generic] drug is the same as the labeling approved for the listed drug." 21 U.S.C. § 355(j)(2)(A)(v). In addition, the label of any approved prescription drug must contain the information that it is available only by prescription; such a drug "shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol 'Rx only'." 21 U.S.C. § 353(b)(4)(A). According to the FDCA, a drug is mislabeled "if its labeling is false or misleading in any particular." 21 U.S.C. § 352(a).

It is undisputed that the defendants' products are approved for sale on a prescription-only basis. The defendants state that because their ANDA's were based upon the approved NDA which allowed for the marketing of Polyethylene Glycol 3350 as a prescription-only drug, the defendants' products labels are required by the FDA and FDCA to indicate that the products are available only by

prescription. *See* 21 U.S.C. § 355(j)(2)(A)(v). Given that the FDA and FDCA require the "prescription only" statements on the defendants' products' labels, the defendants argue that any challenges to their labeling must be addressed by the FDA, not the court. *See* 71 Fed. Reg. 3922, 3934 (Jan. 24 2006) ("the determination whether labeling revisions are necessary is, in the end, squarely and solely FDA's, under the [FDCA].").

Schering-Plough contends that the FDA has already addressed the labeling issue in this case, and "[b]ecause the Agency has already spoken, there is no concern of judicial interference." (Pl.'s Resp. Br. 15-16.) Therefore, Schering-Plough asserts, the court should be permitted to rule on its Lanham Act claim. In support of this position, Schering-Plough cites to letters sent on or about April 20, 2007, from Gary J. Buehler ("Buehler"), Director of the Office of Generic Drugs within the FDA's Center for Drug Evaluation and Research, to the defendants. (Arent Decl. Ex. 1; Ellison Decl. Ex. 1; Freathy Decl. Ex. 2 (collectively the "FDA letters").)[1] The FDA letters state that each of the defendants' "Rx product, which bears the 'Rx only' symbol, is misbranded and may not be legally marketed." (*Id*.) Defendant Schwarz responded to this letter by sending a letter to the FDA indicating that Schwarz disagreed with the position taken by Buehler, and, notwithstanding that disagreement, Schwarz was prepared to withdraw its Polyethylene Glycol 3350 product, GlycoLax, from the market "provided that FDA agrees to exercise its

[1]The court may take judicial notice of the FDA letters submitted by the parties. *See Fornalik v. Perryman*, 223 F.3d 523, 529 (7th Cir. 2000).

enforcement discretion to permit [Schwarz] to sell off the existing GLYCOLAX inventory for 6 months from the date of this letter." (Ellison Decl. Ex. 2.) In a letter dated July 19, 2007, another FDA employee, Michael M. Levy, who is the Director of the Division of New Drugs and Labeling Compliance within FDA's Center for Drug Evaluation and Research, stated: "we do not agree with the arguments" set forth in the June 25, 2007 letter, and, notwithstanding that disagreement, "we are prepared to grant your request for enforcement discretion to market prescription GlycoLax until December 25, 2007." (*Id*. at Ex. 3.) Schering-Plough argues that the FDA letters demonstrate that its Lanham Act claim does not raise undecided issues under the FDCA; rather, the FDA has determined that the "Rx only" statements on the defendants' products' labels refer to Polyethylene Glycol 3350 generally, not to each defendants' individual products. Schering-Plough also argues that the FDA letters demonstrate that, according to the FDA, the defendants' products' labels violate the FDCA because "a drug to which [prescription requirements do not apply] shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the [Rx only] symbol . . . ." 21 U.S.C. § 353(b)(4)(B).

In support of its position that the FDA letters express official FDA determinations, Schering-Plough cites to *Mylan Laboratories, Inc. v. Thompson*, 389 F.3d 1272 (D.C. Cir. 2004), where the D.C. Circuit deferred to agency letters to private parties. However, the letter at issue in *Mylan* was substantially different from the FDA letters cited by Schering-Plough. Specifically, the letter at issue in *Mylan* had legal consequences; it effectively revoked a final approval of Mylan's ANDA for

a generic drug by changing it to "tentative approval," and had the immediate legal consequence that Mylan could not market its generic drug at that time. *Id.* at 1281-82. Here, the FDA letters cited by Schering-Plough did not revoke any approvals of the defendants' products or otherwise purport to mandate any immediate legal consequences. *Cf. See Western Illinois Home Health Care v. Herman*, 150 F.3d 659, 663 (7th Cir. 1998) (holding that a letter from the Department of Labor was final and reviewable, whereas the opinions and letters in other cases were not final and reviewable because of "the absence there of immediate legal consequences for the regulated party."). In addition, as opposed to the FDA letters cited by Schering-Plough, the *Mylan* letter did not address withdrawal of approval of a drug product for one of the reasons specified in 21 U.S.C. § 355(e). *Mylan*, 389 F.3d at 1281-82. Thus, unlike here, in *Mylan* there was no explicit statutory mechanism for the FDA to utilize in effecting that withdrawal of approval. *Id.*

Schering-Plough also submitted *Axcan Sandipharm Inc. v. Ethex Corp.*, 2007 WL 3095367 (D. Minn. Oct. 19, 2007) as supplemental authority. The court in *Axcan* acknowledged that "where a claim requires interpretation of a matter that is exclusively within the jurisdiction and expertise of the FDA and FDCA, plaintiffs cannot use the Lanham Act as a backdoor to private enforcement." *Id.* at 4. However, the court in *Axcan* concluded that because it was required to interpret the "*generally understood meanings* of the terms 'generic equivalence' and 'substitute,' and not the FDA's definition of 'equivalence'" the case did not stray into the FDA's domain. *Id.* at 5 (emphasis in original). In the instant case, unlike the plaintiff's

claims in *Axcan*, Schering-Plough's Lanham Act claim requires the court to infringe upon the FDA's right to determine how the defendants' approved Polyethylene Glycol 3350 products should be labeled.

In considering the defendants' motions to dismiss, the court must accept Schering-Plough's complaint's well-pleaded factual allegations as true and draw reasonable inferences from those allegations in Schering-Plough's favor. *See Transit Express, Inc. v. Ettinger*, 246 F.3d 1018, 1023 (7th Cir. 2001). Even assuming Schering-Plough's factual allegations are true, a ruling on the merits of Schering-Plough's Lanham Act claim would require the court to usurp the FDA's responsibility for interpreting and enforcing the agency's regulations. Jurisdiction for the regulation of prescription-only and over-the-counter drug marketing is vested jointly and exhaustively in the FDA and the FTC, and is divided between them by agreement. *Sandoz*, 902 F.2d at 231. Here, the FDA letters cited by Schering-Plough indicate that, in the opinions of the FDA officials who wrote the letters, the defendants' products are misbranded. However, pursuant to the FDA's own regulations, the FDA has not yet taken any official position concerning the labeling of the defendants' products to which the court can defer.

Congress has established a specific procedure that the FDA must follow in order to withdraw its approval of a drug product based on false or misleading labeling. Specifically, 21 U.S.C. § 355(e) governs the withdrawal of approval for a drug on the basis that "the labeling of such drug . . . is false or misleading." *Id.* Under this statute, the FDA "may . . . after due notice and opportunity for hearing to

the applicant, withdraw the approval of an application . . . if the Secretary finds . . . the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading." *Id.* The FDA letters cited by Schering-Plough did not provide the defendants the opportunity for a hearing regarding the labeling of their products or the withdrawal of FDA approval for their products. Therefore, even if the FDA had purported to make an agency determination through the letters that it had withdrawn its approval of the defendants' products, because such a determination would not have been in compliance with the explicit statutory requirements, the determination could not be considered an official agency determination to be afforded deference.

Indeed, several courts have recognized that letters such as those cited here do not constitute an official agency determination. *See Herman*, 150 F.3d at 662 ("An agency action is not final if it is only 'the ruling of a subordinate official,' or 'tentative.' The core question is whether the agency has completed its decisionmaking process, and whether the result of that process is one that will directly affect the parties.") (quoting *Franklin v. Massachusetts*, 505 U.S. 788, 796-97 (1992); *see also Dietary Supplement Coalition, Inc. v. Sullivan*, 978 F.2d 560, 562-63 (9th Cir. 1992) ("'[T]he type of informal letter issued by the FDA . . . does not constitute . . . formal or final agency action . . . .'") (quoting *Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1377 (9th Cir. 1983)), *cert. denied*, 508 U.S. 906 (1993); *Genendo Pharmaceutical N.V. v. Thompson*, 308 F. Supp. 2d 881, 885 (N.D. Ill. 2003) (statements of agency officials below the Commissioner "do not rise to the level of final agency action -- even when they are contained in warning letters or

other official regulatory correspondence."); *Summit Tech. Inc.*, 922 F. Supp. at 306 ("regardless of any warning letters that the FDA may have sent to defendants, it is clear that the FDA has not completed this investigation."). Furthermore, pursuant to 21 C.F.R. § 10.85(k),"[a] statement or advice given by an FDA employee . . . is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed." *Id.*

As noted above, pursuant to the defendants' ANDA's and the FDCA, the defendants' Polyethylene Glycol 3350 products' labels were required by the FDA to indicate that the products were available only by prescription. *See* 21 U.S.C. §§ 353(b)(4)(A) and 355(j)(2)(A)(v). A review of the FDA letters cited by Schering-Plough and the FDA's own regulations reveals that the FDA letters did not constitute an agency "determination" and that the marketing and labeling of the defendants' Polyethylene Glycol 3350 products is still an open question. By requesting the court to determine whether the defendants can continue to market their prescription-only Polyethylene Glycol 3350 products, Schering-Plough is in effect asking the court to step into the shoes of the FDA. The simultaneous marketing of the defendants' prescription-only Polyethylene Glycol 3350 products and Schering-Plough's over-the-counter Polyethylene Glycol 3350 product, in addition to the labeling of those products, raises questions properly addressed by the FDA, not the court. *See Sandoz*, 902 F.2d at 231; *see also* 71 Fed. Reg. 3922, 3934 ("the determination

whether labeling revisions are necessary is, in the end, squarely and solely FDA's, under the [FDCA]."). Accordingly, because the FDA has not yet made a final determination regarding these marketing and labeling issues, and because Schering-Plough's Lanham Act claim would require this court to "determine preemptively how a federal agency will interpret and enforce its own regulations," the court is obliged to dismiss Schering-Plough's Lanham Act claim. *Sandoz*, 902 F.2d at 231. Schering-Plough is free to petition the FDA to resolve the alleged labeling violations. *See, e.g., id.* at n.10.

Although Schering-Plough did not address some of the arguments raised against its state law claims, because the court is obliged to dismiss Schering-Plough's sole federal claim, the court will relinquish jurisdiction over the remaining state claims under 28 U.S.C. § 1367(c)(3). *See Williams v. Rodriguez*, 509 F.3d 392, 404 (7th Cir. 2007); *Groce v. Eli Lilly & Co.*, 193 F.3d 496, 501 (7th Cir. 1999) ("it is the well-established law of this circuit that the usual practice is to dismiss without prejudice state supplemental claims whenever all federal claims have been dismissed prior to trial.").

Accordingly,

IT IS ORDERED that the plaintiff's motion for partial summary judgment (Docket # 19) be and the same is hereby **DENIED**;

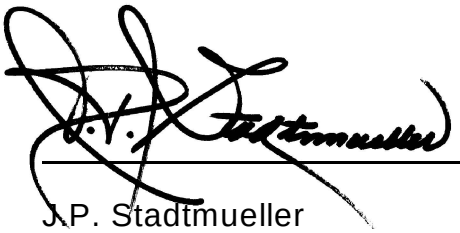
IT IS FURTHER ORDERED that the defendants' motions to dismiss (Docket #'s 52, 53, 59) be and the same are hereby **GRANTED**; Count I of the plaintiff's complaint be and the same is hereby **DISMISSED** with prejudice; the plaintiff's

remaining state claims, Counts II-IV, be and the same are hereby **DISMISSED** without prejudice pursuant to 28 U.S.C. § 1367(c)(3).

The clerk of court is directed to enter judgment accordingly.

Dated at Milwaukee, Wisconsin, this 29th day of February, 2008.

BY THE COURT:



J.P. Stadtmueller
U.S. District Judge