UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN

WYETH,

Plaintiff,

v.

Case No. 09-11726-LPZ-MKM

Hon. Lawrence P. Zatkoff

SUN PHARMACEUTICAL INDUSTRIES LTD. and **CARACO PHARMACEUTICAL LABORATORIES LTD.**,

Defendants.

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DEFENDANTS SUN PHARMACEUTICAL INDUSTRIES LTD.'S AND CARACO PHARMACEUTICAL LABORATORIES LTD.'S MOTION TO DISMISS THE COMPLAINT FOR FAILURE TO STATE A CLAIM UPON WHICH RELIEF MAY BE GRANTED

Defendants Sun Pharmaceutical Industries Ltd. and Caraco Pharmaceutical Laboratories Ltd. move this Honorable Court to dismiss Wyeth's complaint alleging false advertising under the Lanham Act, 15 U.S.C. § 1125 (2009), unfair competition, tortious interference with business expectancy and deceptive trade practices under the Michigan Consumer Protection Act, Mich. Comp. Laws §445.903, for failure to state a claim upon which relief may be granted pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure.

The grounds for this motion are set forth in the accompanying memorandum of law attached hereto.

Respectfully submitted,

July 6, 2009

By: /s/ Lauren S. Albert

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DEFENDANTS SUN PHARMACEUTICAL INDUSTRIES LTD.'S AND CARACO PHARMACEUTICAL LABORATORIES LTD.'S MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS THE COMPLAINT FOR FAILURE TO STATE A CLAIM UPON WHICH RELIEF MAY BE GRANTED

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Defendants Sun Pharmaceutical Industries Ltd. and Caraco Pharmaceutical Laboratories Ltd. (collectively "Sun") move pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure to dismiss the Complaint in the above-entitled action (the "Complaint") for failure to state a claim upon which relief can be granted.

In accordance with Local Rule 7.1, on June 29, 2009, Chad Landmon, counsel for Sun, contacted Alexandra McTague, counsel for Wyeth, explaining the nature of the motion and its legal basis and seeking concurrence in the relief sought in the motion. Wyeth's counsel declined to grant concurrence. Thus, the filing of this motion is necessary.

ISSUES PRESENTED

Whether Wyeth's claims in the Complaint, which are grounded in alleged "false and misleading statements" in Sun's FDA-regulated product package insert, are an improper attempt to seek enforcement for violations of the Federal Food and Drug Cosmetic Act ("FDCA"), 21 U.S.C. § 352 (2009), which expressly provides that there is no private right of action, 21 U.S.C. § 337(a) (2008).

Whether Wyeth's Complaint is defective because Wyeth claims that the alleged "false and misleading statements" are made only in the product package insert and thus are seen by the consumer only after purchasing the product and therefore cannot influence his or her buying decision, a necessary element of a Lanham Act claim.

Whether Wyeth fails to state a claim for unfair competition under the common law because the alleged "false and misleading statements" do not constitute unfair competition.

MOST APPROPRIATE AUTHORITY FOR RELIEF SOUGHT

- Private parties cannot bring an action for alleged violations of the FDCA and corresponding FDA regulations, and similarly cannot use the Lanham Act and related state laws to circumvent this statutory prohibition. 21 U.S.C. § 337(a); Mead Johnson & Co. v. Abbott Lab., 209 F.3d 1032, 1034 (7th Cir. 2000); Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc., 547 F. Supp. 2d 939, 940-41 (E.D. Wis. 2008); Pediamed Pharm., Inc. v. Breckenridge Pharm., Inc., 419 F. Supp. 2d 715, 726 n.14 (D. Md. 2006).

- FDA approved the marketing and sale of Sun's drug product, and correspondingly approved Sun's product package insert containing the very language Wyeth challenges here, 21 U.S.C. § 355(j)(2)(A)(v), 21 C.F.R. § 314.94 (a)(8)(iii) (2009); it is for FDA, not this court, to decide whether that information is false or misleading rendering the drug misbranded. 21 U.S.C. § 355(e); 21 C.F.R. § 201.10(c)(2); Schwarz Pharma, Inc., 547 F. Supp. 2d at 940-41. As such, Wyeth's claims should be dismissed.

- Wyeth's claims should also be dismissed because they fail to plead a necessary element of a false advertising claim – that the deception had a material effect on purchasing decisions because the allegedly false statements are in the package insert, which is not seen by the consumer until after purchase. See Am. Counsel of Certified Podiatric Physicians and Surgeons v. Am. Board of Podiatric Surgery, Inc., 185 F.3d 606, 613 (6th Cir. 1999). Wyeth's conclusory allegations regarding consumers' alleged reliance on the insert are insufficient to state a claim. Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 554-555 (2007).

- Wyeth's unfair competition claim should also be dismissed for failure to state a claim because the alleged "false and misleading statements" do not constitute unfair competition as recognized by Michigan common law. Wilcom Pty. Ltd. v. Endless Visions, 128 F. Supp. 2d 1027, 1033 (E.D. Mich. 1998); Pennwalt Corp. v. Zenith Labs., Inc., 472 F. Supp. 413, 418 (E.D. Mich 1979).

INTRODUCTION

This case represents Wyeth's second attempt to keep Sun's pantoprazole sodium delayed-release tablets from competing with Wyeth's billion-dollar Protonix® drug product. Wyeth originally sued Sun for patent infringement in the District of New Jersey, losing a motion for a preliminary injunction in a decision that was recently affirmed by the Federal Circuit Court of Appeals. After failing there, Wyeth now brings this belated action over a year after Sun first started marketing its product in order to forestall what its patents cannot. Under the guise of asserting claims for false advertising under the Lanham Act, unfair competition, tortious interference and deceptive trade practices under the Michigan Consumer Protection Act, Wyeth seeks to have this Court do the work of FDA. Wyeth's attempt should be rejected, and the Complaint should be dismissed.

Wyeth asserts that Sun's product contains pantoprazole sodium monohydrate ("Monohydrate") as the active ingredient, while Sun's package insert states that the product contains pantoprazole sodium sesquihydrate ("Sesquihydrate") as the active ingredient. (Compl. ¶¶ 13, 15, 16.) The language in the package insert that Wyeth refers to was established after FDA reviewed the content of Sun's Abbreviated New Drug Application ("ANDA"), including the package insert. Any evaluation, or re-evaluation, of the appropriate language in the package insert is determined under the FDCA by FDA. Wyeth, however, would have this Court make this determination instead. But, there is no private right of action under the FDCA. Instead,

FDA has the exclusive jurisdiction to determine the appropriate language in a drug product's package insert.[1]

Moreover, the core remedies Wyeth seeks are remedies that only FDA can impose. Wyeth asks this Court either to order that Sun not sell its product allegedly containing a Monohydrate with an insert for Sesquihydrate or change its insert to state that its product contains a Monohydrate. (Compl., Request for Relief No. 2.) FDA has extensive regulations governing the contents of drug products and labeling, and a manufacturer cannot change the language of a product insert without FDA approval. See, e.g., 21 C.F.R. §§ 201.10(c)(2), 314.70(a)-(b), 314.94(a)(8), 314.125(b)(6). In addition, Congress tasked FDA with removing mislabeled products from the market. The Court cannot and should not interfere with FDA's role in this intricately-regulated industry.

Furthermore, the only allegedly "false and misleading statements" referenced in Wyeth's Complaint appear in Sun's product package insert. (See Compl. ¶¶ 14, 15, 21, 26, 31, 39, 43.) The Lanham Act claim asserted in the Complaint is grounded on Wyeth's allegations that the statements in the package insert have "influenced consumers' purchasing decisions" and have thus harmed Wyeth. (Id. ¶¶ 28, 29, 33, 34, 40, 41, 45, 46.) The package insert, however, is seen by the consumer only after he or she buys the product; it does not have an effect on his or her decision to buy the product. Thus, a crucial element of the Lanham Act claim asserted by Wyeth is conclusory and simply unsupported by the Complaint.

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[1] In fact, FDA is currently in contact with Sun regarding these very issues. If the Court should be interested in further details regarding the nature of Sun's contacts with FDA on these issues, Sun would, of course, be willing to share such information under seal with an appropriate protective order governing Wyeth's treatment of the information.

Finally, Wyeth fails to state a claim for unfair competition under Michigan common law because the alleged misrepresentations do not constitute unfair competition. Under Michigan common law, a cause of action for unfair competition is limited to palming off or to a false designation of origin. Because Wyeth does not allege that Sun engaged in either of these actions, Wyeth's unfair competition claim should be dismissed.

FACTUAL AND REGULATORY BACKGROUND

Before marketing a new drug in the United States, a manufacturer must submit a New Drug Application ("NDA") to FDA, and FDA must approve it. 21 U.S.C. § 355(b). In 2000, FDA approved Wyeth's NDA to market and sell pantoprazole sodium delayed-release tablets under the brand name Protonix® for the treatment of various gastrointestinal disorders. (Compl. ¶¶ 9, 11.) In accordance with the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 301, 355, 360cc and 35 U.S.C. §§ 156, 271, 282 (collectively "Hatch-Waxman Act")), Wyeth enjoyed over seven years of regulatory exclusivity[2] for the sale of Protonix®, earning nearly $2 billion in annual sales. (Compl. ¶ 10.)

Before marketing a generic version of a drug in the United States, a manufacturer must submit an ANDA to FDA, and FDA must approve it. 21 U.S.C. § 355(j). The ANDA applicant must provide FDA with extensive data and information and must demonstrate, among other things, the following:

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[2] Protonix was awarded new chemical entity exclusivity, whereby ANDA applicants are prohibited from filing their applications with FDA for a period of four to five years after Wyeth received FDA approval. See 21 U.S.C. § 355(c)(3)(E)(ii); 21 C.F.R. § 314.108(b)(2). When Wyeth filed patent infringement suits against such ANDA filers under the patent litigation structure set forth in the Hatch-Waxman Act, FDA was prohibited from approving such ANDAs for a period of seven and a half years after Wyeth's NDA was approved (or an earlier court decision against the patents at issue). 21 U.S.C. § 355(c)(3)(E)(ii); 21 C.F.R. § 314.107(b)(3)(B).

- the proposed product has the "same" active ingredient as in the NDA product, 21 U.S.C. § 355(j)(2)(A)(ii), 21 C.F.R. § 314.94(a)(5)(i);

- the dosage form and strength of the proposed product are the same as in the NDA product, 21 U.S.C. § 355(j)(2)(A)(iii), 21 C.F.R. § 314.94(a)(6)(i);

- the proposed product is bioequivalent to the NDA product, 21 U.S.C. § 355(j)(2)(A)(iv), 21 C.F.R. § 314.94(a)(7)(i); and

- the "labeling proposed for the new drug [in the ANDA] is the same as the labeling approved for the listed [NDA] drug," 21 U.S.C. § 355(j)(2)(A)(v), 21 C.F.R. § 314.94(a)(8)(iii).

The ANDA review process is very extensive and requires FDA to review a significant amount of data and other information relating to the proposed ANDA product. For example, an ANDA applicant is required to submit the following information in order to demonstrate that the active ingredient in the ANDA product is the "same" as the active ingredient in the NDA product:

> A full description of the drug substance including its physical and chemical characteristics and stability; the name and address of its manufacturer; the method of synthesis (or isolation) and purification of the drug substance; the process controls used during manufacture and packaging; and the specifications necessary to ensure the identity, strength, quality, and purity of the drug substance and the bioavailability of the drug products made from the substance, including, for example, tests, analytical procedures, and acceptance criteria relating to stability, sterility, particle size, and crystalline form. The application may provide additionally for the use of alternatives to meet any of these requirements, including alternative sources, process controls, and analytical procedures. Reference to the current edition of the U.S. Pharmacopeia and the National Formulary may satisfy relevant requirements in this paragraph.

21 C.F.R. § 314.50(d)(1)(i). See also 21 C.F.R. § 314.94(a)(9)(i) (requiring ANDA filer to submit the information required by Section 314.50(d)(1)).

In addition to providing data relating to the active ingredient, an ANDA applicant is also required to submit the proposed labeling for the product and demonstrate that it "is the same as the labeling approved for the listed drug" by showing a side-by-side comparison of the product inserts for the two products. 21 U.S.C. § 355(j)(2)(A)(v); 21 C.F.R. § 314.94(a)(8)(iv). Detailed information is also required relating to the inactive ingredients, manufacturing process and bioavailability of the proposed product. See, e.g., 21 C.F.R. § 314.94.

In 2004, Sun submitted an ANDA to FDA, seeking approval for its bioequivalent pantoprazole product. (Compl. ¶ 12.) After Sun filed its ANDA, Wyeth and Altana Pharma AG sued Sun for patent infringement in the U.S. District Court for the District of New Jersey (Docket No. 04-02355), in accordance with the patent dispute resolution mechanism established by the Hatch-Waxman Act. See 21 U.S.C. § 355(j); 35 U.S.C. § 271(e). On September 6, 2007, the court denied Wyeth's motion for a preliminary injunction, finding that defendants raised a "sufficiently persuasive" and "substantial argument" that the pantoprazole compound patent was obvious in view of the prior art. Altana Pharma AG v. Teva Pharms. USA, Inc., 532 F. Supp. 2d 666, 677-79, 680-81 (D.N.J. 2007), aff'd, 566 F.3d 999 (Fed. Cir. 2009).

In 2007, FDA approved Sun's ANDA, and Sun began to market its product in 2008. (Compl. ¶ 13.) Significantly for purposes of this case, in approving Sun's ANDA, FDA determined that the active ingredient in Sun's ANDA product is the "same" as the active ingredient in Wyeth's product. 21 U.S.C. § 355(j)(2)(A)(ii); 21 C.F.R. § 314.94(a)(5)(i). The language in the package insert was established after FDA reviewed the contents of Sun's ANDA and its package insert to determine "sameness." See 21 U.S.C. § 355(j)(2)(A)(ii); 21 C.F.R. § 314.94(a)(5)(i). FDA's approval of the product insert in conjunction with its review of Sun's

product testing data constitutes FDA's determination that the label is not false and misleading. See 21 C.F.R. § 314.125(b)(6) (stating that FDA may refuse to approve an ANDA if the "proposed labeling is false or misleading in any particular").

ARGUMENT

Wyeth's Complaint should be dismissed because Wyeth is improperly attempting to have this Court step into the shoes of FDA. There is no private right of action under the FDCA, and the alleged mislabeling that forms the basis of the Complaint should properly be addressed by FDA, not this Court. In fact, numerous courts have dismissed similar claims, recognizing that it is improper for courts to usurp FDA's responsibility to enforce its intricate regulatory scheme. See, e.g., Mead Johnson & Co. v. Abbott Lab., 209 F.3d 1032, 1034 (7th Cir. 2000); Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc., 547 F. Supp. 2d 939, 940-41 (E.D. Wis. 2008); Pediamed Pharm., Inc. v. Breckenridge Pharm., Inc., 419 F. Supp. 2d 715, 726 n.14 (D. Md. 2006). Moreover, because the product insert is the only source for the alleged "false and misleading statements" referenced by Wyeth, the Complaint fails to state a claim under the Lanham Act. Finally, Wyeth fails to state a claim for unfair competition under the common law because the alleged misrepresentations do not constitute unfair competition.

In considering a motion to dismiss under Rule 12(b)(6), the court must construe the complaint in a light most favorable to the plaintiff, and accept all of the factual allegations as true. Bird v. Parsons, 289 F.3d 865, 871 (6th Cir. 2002); Wolfington v. Detroit City Pub. Sch., No. 99-75872, 2000 U.S. Dist. LEXIS 19165, at *4 (E.D. Mich. Nov. 22, 2000) (Zatkoff, J.). A motion to dismiss under Rule 12(b)(6) should be granted if it appears beyond doubt that the

plaintiff can prove no set of facts in support of his claim that would entitle him to relief. Bird, 289 F.3d at 871; Wolfington, 2000 U.S. Dist. LEXIS 19165, at *4.

I. THE FDCA AND FDA REGULATIONS PRECLUDE WYETH'S CLAIMS

All four counts of Wyeth's Complaint are grounded in the alleged "false and misleading" statements in Sun's product insert regarding the form of the active ingredient. By making these claims, Wyeth is essentially asking the Court to usurp the role Congress gave to FDA exclusively. Determining whether Sun's insert is false or misleading, and the remedy requested by Wyeth if it is, will require the Court to delve into the work FDA conducted in approving Sun's ANDA and its procedures for determining whether a product is misbranded. As discussed above, in approving Sun's ANDA, FDA, in accordance with the requirements under 21 U.S.C. § 355(j)(2)(A)(ii) and 21 C.F.R. § 314.94(a)(5)(i), reviewed Sun's ANDA and the package insert and approved them.

In its Complaint, Wyeth now asks this Court either to require Sun to change its insert to state that its product contains a Monohydrate rather than a Sesquihydrate or cease selling its product altogether. (Compl., Request for Relief No. 2.) Both forms of relief are within the exclusive jurisdiction of FDA. FDA prohibits changes to labels on ANDA approved products without its permission and only FDA can order that mislabeled or unapproved pharmaceuticals be removed from the market. 21 U.S.C. §§ 335(e), 337(a); 21 C.F.R. § 314.70(a)(1), (b)(2)(iv)-(v). The proper forum for Wyeth to raise its concerns is through FDA, rather than this Court.[3] See 21 C.F.R. §§ 10.30, 314.200(c)(3).

[3] As previously mentioned, FDA is, in fact, in contact with Sun about these very issues.

A. FDA Must Approve Changes to Labels on ANDA-Approved Products

Sun cannot simply modify its product insert, and it is improper for this Court to step into FDA's shoes and order such a modification. During the ANDA review process, Sun provided FDA with extensive data on the ingredients in its product. After analyzing that data, FDA found that Sun's proposed product had the same active ingredient as Wyeth's product and was bioequivalent to Wyeth's product. 21 U.S.C. § 355(j)(2)(A)(iv); 21 C.F.R. § 314.94(a)(7)(i). Based on the data submitted by Sun, FDA approved Sun's package insert that stated the product contains a pantoprazole sodium Sesquihydrate. 21 U.S.C. § 355(j)(2)(A)(v); 21 C.F.R. § 314.94(a)(8)(iii).

If the Court were to determine that Sun's label is false and misleading and order Sun to change its label, Sun would be unable to do so without violating the FDCA. "The possibility of such a dilemma demands that classic misbranding claims, such as the one here at issue, be reserved solely for resolution by the FDA." Braintree Labs., Inc. v. Nephro-Tech, Inc., No. 96-2459, 1997 U.S. Dist. LEXIS 2372, at *20-21 (D. Kan. Feb. 26, 1997) (declining to exercise jurisdiction over plaintiff's Lanham Act claim that defendant improperly labeled its product as a dietary supplement because FDA regulations may require use of that language on defendant's label).

B. FDA Will Withdraw ANDA Approval if a Label Is False

FDA is tasked with withdrawing approval of an ANDA if it finds that the manufacturer introduced or attempted to introduce a misbranded drug into commerce. 21 U.S.C. § 355c(a)(2) (2008). In fact, the FDCA and FDA regulations provide a procedure for FDA to revoke ANDA

approval when new information reveals that the label approved with the ANDA is false or misleading:

> [A]fter due notice and opportunity for hearing to the applicant . . . if the Secretary finds . . . (3) that on the basis of *new information* before him, evaluated together with the evidence before him when the application was approved, *the labeling of such drug*, based on a fair evaluation of all material facts, *is false or misleading in any particular* and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based.

21 U.S.C. § 355(e) (emphasis added).

FDA may investigate whether a product is misbranded as a result of a variety of sources of information, including through third party submissions or a citizen's petition, avenues that are available to Wyeth. See 21 C.F.R. §§ 10.30, 314.200(c)(3). Once FDA begins an investigation, it follows several procedural steps to determine whether to revoke ANDA approval. First, the Director of the Center for Drug Evaluation and Research must deliver "general" or "specific" notice to the ANDA filer stating the reasons for the proposed withdrawal. See 21 C.F.R. § 314.200(a)(1), (b)(1). One of those reasons may include that the ANDA-approved label is false or misleading because of a falsely stated active ingredient. See 21 U.S.C. § 355(e); 21 C.F.R. § 201.10(c)(2) ("The labeling of a drug may be misleading by reason . . . of . . . [f]ailure to reveal . . . [a] fact with respect to[] an ingredient present in such drug, when such . . . fact is material in the light of the representation that such ingredient is present in such drug.").

Once notice is given, the filer may seek a hearing at which it may present all studies and other evidence demonstrating that its label is not false or misleading. 21 C.F.R. § 314.200(c), (d). Third parties also may submit comments. See id. at § 314.200(c)(3). The Director then

makes a recommendation to the Commissioner of Food and Drugs ("Commissioner") as to whether to grant a hearing or potentially consider summary judgment for the filer or FDA. See id. at § 314.200(f), (g). If the Commissioner then denies a hearing or the opportunity is waived, FDA will issue a notice withdrawing approval and declare all products unlawful. See id. at § 314.200(h). If the hearing is granted, the Commissioner will then either order the withdrawal of the ANDA or allow it to remain in place. See 21 C.F.R. § 10.55(b)(2)(iii).

In fact, FDA is in contact with Sun on this very issue. "When and if a false advertising claim strays too close to the exclusive enforcement domain of the FDA, it cannot stand." Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc., 547 F. Supp. 2d 939, 944 (E.D. Wis. 2008) (citations omitted). Such claims would allow a private litigant to interfere with FDA's own investigatory and prosecutorial function. See Summit Tech., Inc. vs. High-Line Med. Instruments Co., Inc., 922 F. Supp. 299, 306 (C.D. Cal. 1996).

C. The Court Cannot Step into FDA's Shoes

There is no private right of action under the FDCA. 21 U.S.C. § 337(a).[4] Instead, only the federal government by way of either FDA and/or the Department of Justice, can bring proceedings to enforce or restrain violations of the FDCA. Id. To allow private enforcement would eradicate "'the major advantages of enforcement through [FDA] . . . , including expertise, ability to solicit comment from appropriate sources, direct representation of the public interest, and a unitary enforcement policy.'" Braintree Labs., 1997 U.S. Dist. LEXIS 2372, at *9

[4] "Except as provided in subsection (b) of this section [relating to suits brought by states], all such proceedings for the enforcement or to restrain violation of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a).

(quoting National Women's Health Network, Inc. v. A.H. Robins Co., 545 F. Supp. 1177, 1180 (D. Mass. 1982)).

In order to circumvent this prohibition against private enforcement of the FDCA, Wyeth brings this case under the Lanham Act and state competition laws to have this Court interpret and apply the FDCA and FDA regulations. To determine the viability of Wyeth's claims, however, this Court will have to evaluate the labeling approved by FDA. In such circumstances, courts have declined jurisdiction. See, e.g., Summit, 922 F. Supp. at 306. Such claims would "usurp the FDA's discretionary role in the application and interpretation of its regulations." Id. See also Mead Johnson, 209 F.3d at 1034 ("Requirements along the lines of a package insert with medical details are the province of regulations issued by [FDA], not of litigation under the Lanham Act."); Pediamed Pharm., 419 F. Supp. 2d at 726 n.14 (Lanham Act claim dismissed because it was premised on required active ingredient language); Rita Med. Sys., Inc. v. Resect Med., Inc., No. 05-03291, 2006 U.S. Dist. LEXIS 52366, at *9-11 (N.D. Cal. July 17, 2006) (denying motion for a preliminary injunction based on a Lanham claim where FDA approved the way the device was marketed); Braintree Labs., 1997 U.S. Dist. LEXIS 2372, at *20-21 (where the FDCA defined "dietary supplement," action challenging use of such on a non-approved drug precluded).

In a case that is on all fours with the case at bar, the court found that FDA had primary jurisdiction to determine whether defendant's label was false or misleading. In Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc., 547 F. Supp. 2d 939, 940-41 (E.D. Wis. 2008), the plaintiff claimed "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")." FDA had originally approved plaintiff's NDA for sale by prescription only. Id. at 941. Prior to approving the sale of plaintiff's Polyethylene Glycol 3350 for sale over-the-counter, FDA approved defendants' ANDA for Polyethylene Glycol 3350 for sale by prescription only. Id. Plaintiff alleged that the defendants' use of the phrase "prescription only" on their labels constituted false advertising in violation of the Lanham Act because Polyethylene Glycol 3350 was available from plaintiff without a prescription. Id. at 942.

As is true with respect to Sun's ANDA approval, FDA required defendant to show that its label was the same label as the approved drug, i.e., the prescription only Polyethylene Glycol 3350. Id. at 944 (citing 21 U.S.C. § 355(j)(2)(A)(v)). FDA regulations also required defendants to state that their product was 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'.'" Schwarz Pharma, 547 F. Supp. 2d at 944 (citing 21 U.S.C. § 353(b)(4)(A)). In declining to exercise jurisdiction, the court held "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." Schwarz Pharma, 547 F. Supp. 2d at 946. "Jurisdiction for the regulation of prescription-only and over-the-counter drug marketing is vested jointly and exhaustively in the FDA and the FTC . . . . " Id.

Schwarz Pharma and the case at bar present an even stronger case that the court lacks jurisdiction than other cases finding FDA preemption because the former cases involve challenges to language *required* by FDA. Yet even in cases where FDA did not mandate that the product carry any specific labeling, courts have found preemption. See, e.g., Mead Johnson, 209

F.3d at 1034 (claim based on non-mandated advertisement regarding the defendant's infant formula being the "1st choice of doctors" precluded); Pediamed, 419 F. Supp. 2d at 726 n.14 (claim based on listing of active ingredients on unapproved product precluded); Rita Med., 2006 U.S. Dist. LEXIS 52366, at *9-10 (claim based on non-mandated product labeling regarding the compatibility of the parties' devices for tumor treatment precluded); Braintree Labs., 1997 U.S. Dist. LEXIS 2372, at *2 (claim based on non-mandated product label describing product at issue as a dietary supplement precluded).

The few cases allowing Lanham Act claims to proceed where the claim was based on labeling arguably in the purview of FDA are inapposite because, unlike here, those cases do not require interpretation and application of FDA's review and approval of the language on the product package insert. For example, in Grove Fresh Distribs., Inc. v. Flavor Fresh Foods, Inc., 720 F. Supp. 714, 716 (N.D. Ill. 1989), the court allowed plaintiff's Lanham Act claim that defendant falsely represented that its product was 100 percent orange juice from concentrate to proceed. The court held that plaintiff could establish a violation of the Lanham Act even without considering FDA's regulation defining orange juice. Id. Similarly, in Summit Tech., Inc. v. High-Line Med. Instruments Co., 933 F. Supp. 918, 933 n.7 (C.D. Cal. 1996), the court held that plaintiff's claim that defendant falsely represented that its lasers had FDA approval did "not require an interpretation or application of FDA regulations."[5]

Conversely here, Wyeth's mislabeling claim requires extensive analysis into FDA regulations. The very language at issue was reviewed and approved by FDA. It was based on

[5] The court dismissed plaintiff's claims that required the court's interpretation and application of FDA's regulations so as to prevent "usurp[ing] [] FDA's authority." Summit, 933 F. Supp. at 934-37 (dismissing claim, inter alia, that challenged defendant's assertion that its laser importation was legal).

the submission of extensive scientific data. To determine the accuracy of the label therefore requires a review of that same data and analysis of whether FDA rightly or wrongly imposed the language on the insert based on that data. Such a review is within the exclusive jurisdiction of FDA. Therefore, Wyeth's Complaint should be dismissed by this Court.

For the same reasons, Wyeth's state law claims should be dismissed. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 352-53 (2001) (dismissing state claim that would not have been alleged or proven absent the FDCA disclosure requirements); Riley v. Cordis Corp., No. 08-5031, 2009 U.S. Dist. LEXIS 47827, at *51-52 (D. Minn. June 5, 2009) (dismissing state law causes of action including negligent misrepresentation and breach of implied warranty where they could not be established absent the FDCA and FDA requirements regarding medical devices); Andrx Pharms., Inc. v. Biovail Corp., 175 F. Supp. 2d 1362, 1370 (S.D. Fl. 2001) (dismissing deceptive and unfair practices and tortious interference with business relationship claims premised upon the patent listing requirements of the Hatch-Waxman Act), vacated on other grounds, 276 F.3d 1368 (Fed. Cir. 2002); see also Skibniewski v. Am. Home Prods. Corp., No. 99-0842, 2004 U.S. Dist. LEXIS 31014, at *38-39 (W.D. Mo. Mar. 31, 2004) (Wyeth successfully argued that proffered evidence supporting state claims premised on the FDCA and FDA regulations was not permitted).

II. BECAUSE THE INSERTS DO NOT INFLUENCE CONSUMERS' PURCHASING DECISIONS, THE COMPLAINT FAILS TO STATE A CLAIM UNDER THE LANHAM ACT

Wyeth's Lanham Act claim is grounded solely in Sun's alleged "false and misleading statements" in its product insert, which Wyeth alleges "influenced consumers' purchasing decisions." Significantly, Wyeth pleads that the allegedly false statements are only on the

package inserts, (see Compl. ¶¶ 14, 15, 21, 26, 31, 39, 43), which consumers do not see until after they have purchased the product. A necessary element of a false advertising claim under the Lanham Act – that plaintiff show, inter alia, that the deception had a material effect on purchasing decisions – is therefore lacking. See Am. Counsel of Certified Podiatric Physicians and Surgeons v. Am. Board of Podiatric Surgery, Inc., 185 F.3d 606, 613 (6th Cir. 1999) (to state a Lanham Act false advertising claim, the alleged misrepresentation must be "material in that it will likely influence the deceived consumer's purchasing decisions"); Tang v. Putruss, No. 06-12624, 2007 U.S. Dist. LEXIS 74565, at *10-12 (E.D. Mich. Oct. 5, 2007) (same, dismissing claim)).

Under such circumstances, courts have found plaintiffs' Lanham Act claims defective. In Wilchombe v. Teevee Toons, Inc., 515 F. Supp. 2d 1297, 1305-06 (N.D. Ga. 2007), the court rejected the plaintiff's claim that an insert with a CD violated the Lanham Act by incorrectly identifying the composers on the album. The court found that "[t]he public retrieved the CD inserts only after buying the [a]lbum, and therefore they could not have had a material effect on purchasing decisions." Id. at 1306. See also Arlington Video Prods., Inc. v. Fifth Third Bancorp, No. 08-122, 2008 U.S. Dist. LEXIS 51196, at *9-10 (S.D. Ohio May 1, 2008) (dismissing Ohio deceptive practices claim paralleling the Lanham Act where the plaintiff failed to allege that consumers had actually received or saw an advertisement containing the allegedly false or misleading statement); MPC Containment Sys., Ltd. v. Moreland, No. 05-6973, 2006 U.S. Dist. LEXIS 55780, at *8 (N.D. Ill. Aug. 10, 2006) (dismissing Lanham Act false advertising claim, inter alia, where the plaintiff failed to sufficiently allege when the alleged misrepresentation had occurred); Gillette Co. v. Norelco Consumer Prods. Co., 946 F. Supp. 115,

135 (D. Mass. 1996) (package inserts are not advertising or promotion under the Lanham Act because the statements were made inside the product's packaging, seen by consumers after purchase and "did not affect the choice to purchase, that choice having been made at an earlier point."); Marcyan v. Nissen Corp., 578 F. Supp. 485, 506-07 (N.D. Ind. 1982) (the allegedly false misrepresentations in a user's manual provided to the purchaser of the defendant's exercise equipment were not false advertising). Likewise, because the allegedly false statements at issue here are only alleged to be in the package inserts, they cannot influence the consumer's purchasing decision and therefore fail to state a claim for false advertising under the Lanham Act.

Wyeth cannot overcome this dispositive deficiency with its allegation "[u]pon information and belief, [the allegedly false statement on in the inserts] has influenced consumers' decisions . . . " (Compl. ¶ 24.) The Supreme Court in Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 554-555 (2007) and its progeny have made clear that such conclusory statements "are not entitled to be presumed true." That is particularly true here, where the conclusory statement is illogical – how can a package insert be seen prior to purchase? Wyeth fails to allege any facts that make this scenario plausible, thus requiring dismissal. Ashcroft v. Iqbal, 129 S. Ct. 1937, 1951-52 (2009) (dismissing complaint as conclusory); Marangos v. Swett, No. 08-4146, 2009 U.S. App. LEXIS 13998, at *6-7 (3d Cir. June 25, 2009) (affirming dismissal of complaint where the claims were supported by "mere conclusory statements [that] . . . do not permit the court to infer more than a mere possibility of misconduct . . . "); Maldonado v. Fontanes, No. 08-2211, 2009 U.S. App. LEXIS 12716, at *8, *25-26 (1st Cir. June 4, 2009) (dismissing claims that "stop[ped] short of the line between possibility and plausibility of entitlement to relief . . . ").

III. WYETH'S UNFAIR COMPETITION UNDER MICHIGAN'S COMMON LAW CLAIM IS DEFECTIVE

Michigan's common law of unfair competition enforces two theories of liability:

> [(1)] palming off, . . . [involving] the simulation by one person, for the purpose of deceiving the public, of the name, symbols, or devices employed by a business rival, [o]r the substitution of the goods or wares of one person for those of another, thus falsely inducing the purchase of his wares and thereby obtaining for himself the benefits properly belonging to his competitor . . .

or (2) a false designation of origin whereby the defendant's alleged use of a plaintiff's trademark is likely to cause consumer confusion as to the source of the product. See Wilcom Pty. Ltd. v. Endless Visions, 128 F. Supp. 2d 1027, 1033 (E.D. Mich. 1998) (Lanham Act claim elements for false designation of origin are identical to those for same under Michigan unfair competition law); Pennwalt Corp. v. Zenith Labs., Inc., 472 F. Supp. 413, 418 (E.D. Mich 1979) (palming off as one of two theories of liability sustainable under Michigan unfair competition law).

Neither of these theories is applicable to Wyeth's unfair competition claim here because Sun is not accused of palming off Wyeth's Protonix as its own or otherwise utilizing Wyeth's claimed trademarks. Thus, this count should be dismissed for failure to state a claim.

CONCLUSION AND RELIEF REQUESTED

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 6, 2009, a copy of the foregoing Motion to Dismiss and Memorandum of Law in Support of Motion to Dismiss was electronically filed with the Clerk of Court via CM/ECF, which will send notification of such filing to counsel of record as follows:

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