UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

WYETH,

Plaintiff,

v.

Case No. 09-11726
Hon. Lawrence P. Zatkoff

SUN PHARMACEUTICAL INDUSTRIES, LIMITED and CARACO PHARMACEUTICAL LABORATORIES, LIMITED,

Defendants.
_____/

OPINION AND ORDER

AT A SESSION of said Court, held in the United States Courthouse, in the City of Port Huron, State of Michigan, on March 2, 2010

PRESENT: THE HONORABLE LAWRENCE P. ZATKOFF
UNITED STATES DISTRICT JUDGE

I. INTRODUCTION

This matter is before the Court on Defendants' motion to dismiss [dkt 9].[1] The parties have fully briefed the motion. The Court finds that the facts and legal arguments are adequately presented in the parties' papers such that the decision process would not be significantly aided by oral argument. Therefore, pursuant to E.D. Mich. L.R. 7.1(e)(2), it is hereby ORDERED that the motion be resolved on the briefs submitted. For the following reasons, Defendants' motion to dismiss is GRANTED.

[1]Defendants have also filed a motion to file a supplemental brief [dkt 15] in which they alert the Court to the Seventh Circuit's opinion in *Schering-Plough Healthcare Prods., Inc. v. Schwartz Pharma, Inc.*, 586 F.3d 500 (7th Cir. 2009). Plaintiff responded to the motion, noting that it considers additional briefing unnecessary but not objecting so long as it be permitted a responsive brief. Accordingly, the Court GRANTS Defendants' motion to file a supplemental brief, and it has considered both parties' supplemental briefs in deciding the current motion.

II. BACKGROUND

A. Prescription Drug Regulation

The factual basis of Plaintiff's claim is better understood with a brief summary of the Food and Drug Administration's (FDA) regulatory powers under the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq*.

The FDCA was enacted in response to the concern regarding "unsafe drugs and fraudulent marketing[.]" *Wyeth v. Levine*, __ U.S. ___, 129 S. Ct. 1187, 1195 (2009). This legislation granted the FDA the authority to review applications for new drugs and to reject applications for drugs that are deemed unsafe or ineffective. *See id.*; *see also* 21 U.S.C. § 355.

Prior to releasing a new drug in the market, a manufacturer must file a New Drug Application (NDA) with the FDA. *See* § 355(b)(1). The FDCA requires that a NDA include information and reports on the drug's safety, composition, and manufacturing process. *See id*. The manufacturer is also required to submit proposed labeling, patent information, and samples of the drug for testing. *See id*. After receiving the submissions, the FDA reviews the application and renders a decision on the NDA. A drug whose NDA has been approved is sometimes referred to as a "pioneer drug."

In 1984, Congress passed the Hatch-Watchman Amendments to the FDCA in order to "expedite the process by which companies gain approval to sell generic versions of already-approved brand-name drugs." *Parepac Pharm. Co. v. Thompson*, 354 F.3d 877, 879 (D.C. Cir. 2004). To market a generic drug, a manufacturer must file an Abbreviated New Drug Application (ANDA). *See* § 355(j). As part of an ANDA, the manufacturer is required to show that the FDA has previously approved the active ingredient(s) of its generic product. *See* § 355(j)(2)(A)(ii). In

addition, the generic drug must be bioequivalent to the pioneer drug, *see* § 355(j)(2)(A)(iv), and the proposed labeling must be the same as that of the pioneer drug, *see* § 355(j)(2)(A)(v). Finally, the manufacturer must affirm that it is not infringing on a patent for the pioneer drug. *See* § 355(j)(2)(A)(vii).[2] The FDA is required to approve an ANDA for a generic drug with a single active ingredient unless it finds that the "information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug." § 355(j)(4)(C)(i).

To keep medical professionals and the public apprised of approved generic products, the FDA is required to maintain a database of all pioneer drugs and their approved generic equivalents, which is updated monthly. *See* § 355(j)(7)(A). The database is commonly known as the "Orange Book." If a generic drug is listed in the Orange Book, physicians may prescribe that drug as a substitute for a costlier pioneer drug.

B. Plaintiff's Complaint

Plaintiff is a manufacturer of pharmaceuticals, including Protonix, a prescription drug that treats various gastro-intestinal disorders by inhibiting the secretion of gastric acid. The active ingredient of Protonix is pantoprazole sodium sesquihydrate ("sesquihydrate"). As required, Plaintiff submitted a NDA to the FDA demonstrating that Protonix is safe and effective for use. On February 2, 2000, the FDA approved Plaintiff's NDA, which gave Protonix pioneer-drug status, and Plaintiff began to market Protonix. According to Plaintiff, Protonix is one of its most successful products, with annual sales approaching $2 billion prior to the availability of generic versions of

[2]This requirement is the subject of much of the litigation surrounding generic drugs, and Plaintiff is currently contesting the validity of Defendants' patent for their generic product in another proceeding. *See Altana Pharma AG v. Teva Pharm. USA, Inc.*, 532 F. Supp. 2d 666 (D.N.J. 2007), *aff'd*, 566 F.3d 999 (Fed. Cir. 2009) (denying Plaintiff's motion for preliminary injunction).

Protonix (including Plaintiff's own generic version of the drug).

Defendants engage in the same business as Plaintiff, and their portfolio includes a generic version of Protonix. In 2004, Defendants filed an ANDA seeking approval to market their generic version of Protonix. In their ANDA, Defendants informed the FDA that the active ingredient in their product was sesquihydrate—the same active ingredient in Protonix. In September 2007, the FDA approved Defendants' ANDA for generic Protonix. According to Plaintiff, Defendants' product label and packaging insert list sesquihydrate as the product's active ingredient, and Defendants market the product on their website as a generic version of Protonix. The Orange Book identifies Defendants' product as an "AB"-rated generic substitute for Protonix, which indicates that Defendants have "provided adequate studies to establish the bioavailability and the bioequivalence of [their] product." *Schering Corp. v. Vitarine Pharms., Inc.*, 889 F.2d 490, 492 (3d Cir. 1989).

Plaintiff alleges that the active ingredient in Defendants' generic product is not sesquihydrate but instead is pantoprazole sodium monohydrate ("monohydrate"). Plaintiff contends that monohydrate is a polymorph of sesquihydrate, which means that the ingredients have "different crystal forms, and therefore can have different properties, including melting point, stability, dissolution, and bioavailability." Pl.'s Compl. at ¶17. Plaintiff argues that Defendants have violated the Lanham Act, 15 U.S.C. § 1125, and the Michigan Consumer Protection Act, Mich. Comp. Laws § 445.901, by misrepresenting the active ingredient of their generic product. Plaintiff seeks injunctive relief and an award of damages.

III. LEGAL STANDARD

A motion brought pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief may be granted tests the legal sufficiency of Plaintiff's claims. The Court must accept as true

all factual allegations in the pleadings, and any ambiguities must be resolved in Plaintiff's favor. *See Jackson v. Richards Med. Co.*, 961 F.2d 575, 577–78 (6th Cir. 1992). While this standard is decidedly liberal, it requires more than the bare assertion of legal conclusions. *See Advocacy Org. for Patients & Providers v. Auto Club Ins. Ass'n*, 176 F.3d 315, 319 (6th Cir. 1999). Thus, a plaintiff must make "a showing, rather than a blanket assertion of entitlement to relief" and "[f]actual allegations must be enough to raise a right to relief above the speculative level" so that the claim is "plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, 570 (2007). *See also Ashcroft v. Iqbal*, __ U.S. ___, 129 S. Ct. 1937, 1953 (2009) ("Our decision in *Twombly* expounded the pleading standard for 'all civil actions . . . . '").

In deciding a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), this Court may only consider "the facts alleged in the pleadings, documents attached as exhibits or incorporated by reference in the pleadings, and matters of which the [Court] may take judicial notice." 2 James Wm. Moore et al., *Moore's Federal Practice* ¶ 12.34[2] (3d ed. 2000). If, in deciding the motion, the Court considers matters outside the pleadings, the motion will be treated as one for summary judgment pursuant to Fed. R. Civ. P. 56. *See* Fed. R. Civ. P. 12(b).

IV. ANALYSIS

Defendants challenge Plaintiff's complaint on the grounds that: (1) exclusive jurisdiction for Plaintiff's claim rests with the FDA; (2) Plaintiff has failed to state a Lanham Act claim; and (3) Plaintiff has failed to state an unfair competition claim under Michigan law. The Court will focus its analysis on the preclusion issue.

A. Lanham Act

Defendants maintain that this dispute should be resolved by the FDA because the FDCA

does not provide for a private cause of action. Defendants represent that the FDA is currently investigating Plaintiff's allegations, and they opine that the Court should defer to the FDA's investigatory process. Plaintiff does not dispute that the FDA has commenced action; rather, it insists that its claims can be resolved without usurping the FDA's jurisdiction.

This case involves the interplay of two federal statutory schemes: The FDCA and the Lanham Act. The Lanham Act "provides the user of a trade or service mark with the opportunity to register it with the [Patent and Trademark Office]." *KP Permanent Make-Up, Inc. v. Lasting Impression I, Inc.*, 543 U.S. 111, 117 (2004). Once a product is registered in accordance with the Act, the holder of the mark enjoys several statutory protections, including protection from injuries suffered due to false advertising or mislabeling by competitors. *See* 15 U.S.C. § 1125.

Courts have acknowledged the inherent conflict between the FDA's exclusive jurisdiction over prescription drug regulation and the Lanham Act's protection of patents and trademarks involved in prescription drug manufacturing. *See, e.g.*, *Codonics, Inc. v. DatCard Sys., Inc.*, No. 1:08-CV-1885, 2009 WL 2382567, at *4 (N.D. Ohio July 31, 2009) (citing cases). Courts have been cautious not to allow parties to circumvent the FDCA—and, correspondingly, the authority of the FDA—by means of resort to the Lanham Act. *See Braintree Labs., Inc. v. Nephro-Tech, Inc.*, No. 96-2459-JWL, 1997 WL 94237, at *6 (D. Kan. Feb. 26, 1997) ("[A] plaintiff may not use the Lanham Act as an alternative vehicle by which to seek redress for an FDCA violation."). A district court within this circuit recently summarized the issue:

> Most courts, though, have allowed Lanham Act claims for false advertising of food or drugs to proceed, despite applicability of FDA regulations to the allegedly false advertising, when (1) the plaintiff can prove the falsity of the advertising without the use of FDA regulations, such as by reference to a market definition of the term; or (2) the plaintiff can prove the falsity of the advertising through

reference to an unambiguous FDA definition.

Codonics, 2009 WL 2382567, at *4 (footnotes and citations omitted).

B. Active Ingredient

To summarize Plaintiff's central argument, Plaintiff contends that Defendants market their product as containing one active ingredient (sesquihydrate), while in reality, the product contains a different active ingredient (monohydrate). Plaintiff is essentially asking that the Court find either (1) that the FDA erred—or was misled—in approving Defendants' ANDA because their generic product contains a different active ingredient than Protonix; or (2) that Defendants received FDA approval to market sesquihydrate, yet they instead sell a non-approved product with monohydrate as the active ingredient.

Insofar as Plaintiff challenges the FDA's approval of Defendants' ANDA, such a challenge is not properly before the Court. The FDA is a governmental agency, and its decisions, including generic-equivalency determinations, are to be challenged administratively. *See* 5 U.S.C. §701 *et seq.*; s*ee also Zeneca, Inc. v. Shalala*, 213 F.3d 161 (4th Cir. 2000) (challenge to FDA's approval of ANDA); *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313 (D.C. Cir. 1998) (challenge to equivalency determinations of ingredients in generic drug); *Pharmanex, Inc. v. Shalala*, No 2:97CV262K, 2001 WL 741419 (D. Utah Mar. 30, 2001) (manufacturer appealing FDA determination that its dietary supplement required approval).

The other reasonable interpretation of Plaintiff's complaint is that Defendants properly gained approval for sesquihydrate yet are instead selling a product containing monohydrate. This is an extremely serious allegation, as any non-disclosed and non-approved change to an approved drug can result in severe civil and criminal liability. *See* 21 U.S.C. §§ 331, 333(b); *see also United*

States v. Marcus, 82 F.3d 606, 607 (4th Cir. 1996) (affirming sentence for defrauding the United States for adding two unapproved ingredients to generic drug).

Even if Plaintiff could prove these allegations, the FDCA does not provide for a private right of action. *See* 28 U.S.C. § 337; *Bailey v. Johnson*, 48 F.3d 965, 969 (6th Cir. 1995). Therefore, it is solely the FDA's duty to investigate and prosecute allegations of misbranding or adulterating drugs. *See Pediamed Pharms., Inc. v. Breckenridge Pharm., Inc.*, 419 F. Supp. 2d 715, 726–27 (D. Md. 2006) (dismissing claims that competitor's product failed to meet the stated active ingredient percentage and that competitor was required to file a NDA); *Healthpoint, Ltd. v. Stratus Pharms., Inc.*, 273 F. Supp. 2d 769, 799 (W.D. Tex. 2001) (holding that "it is for the FDA to exercise its discretion" to determine whether products were lawfully on the market); *Braintree Labs.*, 1997 WL 94237, at *7 ("The crux of this count is defendants' failure to receive FDA approval under the FDCA. Thus, plaintiff's claim is unmistakably one for direct enforcement of the FDCA, for which no private right of action exists, either under that statute or the common law.").

Moreover, even if the Court construes Plaintiff's complaint as advancing arguments that are not precluded by the above discussion, the Court finds that this is a matter that is better left to the FDA's expertise.

Plaintiff argues that Defendants have labeled their product as containing a different active ingredient than what the product actually contains, the truth of which can be proven without resort to the FDA. Of note, Plaintiff insists that it is not requesting that the Court order Defendants to change their label (which would require FDA approval); rather, Plaintiff seeks an order enjoining Defendants from selling or marketing their product until they gain FDA approval to market a product containing monohydrate as the active ingredient.

Plaintiff suggests that this case is no different than determining whether a "100% orange juice" connotation is misleading when, in fact, the juice contained additional ingredients, *see Grove Fresh Distribs., Inc. v. Flavor Fresh Foods, Inc.*, 720 F. Supp. 714 (N.D. Ill. 1989), whether fruit juice was misbranded because it was misleading in the types of fruits used, *see Pom Wonderful LLC v. Ocean Spray Cranberries, Inc.*, 642 F. Supp. 2d 1112 (C.D. Cal. 2009), or whether a product marketed as containing "1% anthralin cream" contained the advertised percentage of that ingredient, *see Sirius Labs., Inc. v. Rising Pharms., Inc.*, No. 03 C 6965, 2004 WL 51240 (N.D. Ill. Jan. 7, 2004). *See also Genderm Corp. v. Biozone Labs.*, No. 92 C 2533, 1992 WL 220638 (N.D. Ill. Sept. 3, 1992) (allowing Lanham Act claims that product did not contain advertised active ingredient).

The claims in Plaintiff's cited cases, however, could be resolved by simple reference to the applicable FDA regulations, as the FDA had not approved or taken other action regarding the products at issue. For example, the FDA never tested the orange juice in *Grove Fresh* as being 100% pure or approved the active ingredient in the *Genderm* product. Therefore, the parties were free to challenge their competitors' unsubstantiated remarks regarding the quality or content of their products.

When Lanham Act claims require more than comparing products to stated regulations, however, courts have found those claims to encroach upon the FDA's jurisdiction. For example, it is within the FDA's province to determine whether an ingredient labeled as "inactive" should be labeled as "active." *See Sandoz Pharms. Corp v. Richardson-Vicks, Inc.*, 902 F.2d 222, 232 (3d Cir. 1990). *See also Healthpoint, Ltd. v. Ethex Corp.*, 273 F. Supp. 2d. 817, 841–42 (W.D. Tex. 2001) (whether an ingredient must be listed as an active ingredient fell within the FDA's exclusive jurisdiction). Likewise, in *Braintree Labs.*, the court dismissed a claim that a dietary supplement

was misbranded, concluding that "classic misbranding claims, such as the one here at issue, be reserved solely for resolution by the FDA." 1997 WL 94237, at *7. Finally, in *Schering-Plough*, the court deferred to an ongoing FDA inquiry to determine whether an FDA-approved drug label was misbranded when the label advertised the product as "prescription only", yet an over-the-counter version was available. 586 F.3d at 508–09.

Plaintiff's complaint cites from a FDA publication that defines polymorphs and notes that "polymorphic forms of a drug substance . . . can have different chemical and physical properties that can have a direct effect on drug product stability, dissolution, and bioavailability, which ultimately can affect the quality, safety, and efficacy of the drug product." Pl.'s Compl. at ¶17. Plaintiff conveniently omits further reference to that same document, which continues to state that "differences in drug substance polymorphic forms do not render drug substances different active ingredients for the purposes of ANDA approvals within the meaning of the Act and FDA regulations." FDA Guidance for Industry, ANDAs: Pharmaceutical Solid Polymorphism, at p.5 (July 2007), *available at* http://www.fda.gov/downloads/DrugsuidanceComplianceRegulatory Information/Guidances/ucm072866.pdf (last visited Feb. 25, 2010).

Therefore, in order to adjudicate Plaintiff's claims, the Court would be required to interpret FDA regulations regarding the equivalency of polymorphs and predict the FDA's ruling on the issue. Furthermore, a decision in Plaintiff's favor would conflict with the valid FDA approval of Defendants' product—a situation that was not implicated in any of Plaintiff's cited cases. For these reasons, to the extent that Plaintiff's misbranding allegations are properly before the Court, the Court defers to the FDA's expertise over these matters.

C. Generic Equivalency

Plaintiff also challenges Defendants' statements on their website representing their product as a generic equivalent of Protonix.

Courts generally consider Lanham Act claims regarding equivalency representations when those claims are limited to advertising or statements involving comparisons of FDA-regulated products. *See Graceway Pharms. LLC v. River's Edge Pharms. LLC*, No. 08-CV-0067-RWS, 2009 WL 3753586 (N.D. Ga. Nov. 6, 2009); *Healthpoint, Ltd. v. Allen Pharm.*, LLC, No. SA-07-CA-0526-XR, 2008 WL 728333 (E.D. Tex. Mar. 18, 2008); *Axcan Scandipharm, Inc. v. Ethex Corp.*, 585 F. Supp. 2d 1067 (D. Minn. 2007); *Pediamed Pharms.*, 419 F. Supp. 2d 715; *Schwartz Pharma, Inc. v. Breckenridge Pharm., Inc.*, 388 F. Supp. 2d 967 (E.D. Wisc. 2005); *Solvay Pharms., Inc. v. Ethex Corp.*, No. 03-2836, 2004 WL 742033 (D. Minn. Mar. 30, 2004); *Healthpoint*, 273 F. Supp. 2d 817. *But see Ethex Corp. v. First Horizon Pharm. Corp.*, 228 F. Supp. 2d 1048 (E.D. Mo. 2002) (dismissing Lanham Act claim based on marketing of non-FDA-approved prenatal vitamins as generic equivalent).

In none of the above cases, however, did the defending party have the backing of the FDA confirming its equivalency representations. In fact, the lack of an affirmative FDA equivalency determination (*i.e.*, ANDA approval and Orange Book status) was oft-cited as a justification for allowing the Lanham Act claims to proceed. *See, e.g., Graceway Pharms.*, 2009 WL 3753586, at *2; *Healthpoint*, 2008 WL 728333, at *16; *Axcan*, 585 F. Supp. 2d at 1074; *Pediamed Pharms.*, 419 F. Supp. 2d at 726; *Schwartz Pharma*, 388 F. Supp. 2d at 974; *Healthpoint*, 273 F. Supp. 2d at 840.

Here, the FDA has determined that Defendants' product is the generic equivalent of Protonix and the Orange Book recognizes it as such. Plaintiff has not identified, nor has the Court uncovered, a single instance in which a federal court has permitted the manufacturer of a pioneer drug to

challenge generic-equivalency representations under the Lanham Act when the defending party markets a FDA-approved, Orange Book-listed generic version of the pioneer drug. Furthermore, Plaintiff has not pointed to any statement or advertisement that does not directly implicate the FDA's equivalency determination. Allowing Plaintiff's complaint to proceed necessarily questions the validity of the FDA's decisions. Therefore, the Court declines to entertain Plaintiff's generic-equivalency challenges under the Lanham Act.

D. Conclusion

Despite painting its claims as arising under the Lanham Act, Plaintiff's allegations are intertwined with the FDA's authority to regulate prescription drugs. Therefore, the Court finds it appropriate for the FDA to complete its current investigation and determine whether Defendants' marketed product contains the advertised active ingredient and/or whether Defendants' product is the generic equivalent of Protonix. *See Schering-Plough*, 586 F.3d at 505 (there is "no need to guess while the misbranding proceeding is wending its way through the FDA"); *Summit Tech., Inc. v. High-Line Med. Instruments Co., Inc.*, 922 F. Supp. 299, 307 (C.D. Cal. 1996) (dismissing Lanham Act claims that "involve[] the failure to disclose a 'fact,' the truth of which is currently being reviewed and determined by the FDA."). As a result, the Court finds that Plaintiff has "jumped the gun by suing before the FDA addressed the misbranding issue." *Schering-Plough*, 586 F.3d at 510; *see also Sandoz*, 902 F.2d at 231 n.10 ("the fact that [the plaintiff] has been unable to get a quick response from the FDA . . . does not create a claim . . . under the Lanham Act").

If the FDA confirms Plaintiff's suspicions, however, Plaintiff may be able to sustain its Lanham Act claims. Therefore, the Court will dismiss Plaintiff's complaint without prejudice, subject to re-filing following the outcome of the FDA's investigation. *See, e.g.*, *Shering-Plough*,

586 F.3d at 514 (affirming dismissal of Lanham Act claims without prejudice).

V. CONCLUSION

Accordingly, and for the above reasons, IT IS HEREBY ORDERED that Defendants' motion to dismiss [dkt 9] is GRANTED.

It is FURTHER ORDERED that Plaintiff's complaint is DISMISSED WITHOUT PREJUDICE.

IT IS SO ORDERED.

S/Lawrence P. Zatkoff
LAWRENCE P. ZATKOFF
UNITED STATES DISTRICT JUDGE

Dated: March 2, 2010

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of this Order was served upon the attorneys of record by electronic or U.S. mail on March 2, 2010.

S/Marie E. Verlinde
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