UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Arbor Pharmaceuticals, LLC,

Plaintiff,

v.

ANI Pharmaceuticals, Inc.

Defendant.

Civil No. 17-4910 (DWF/LIB)

MEMORANDUM OPINION AND ORDER

Andre T. Hanson, Esq., Katharyn Ann Grant, Esq., and Saul H. Perloff, Esq., Norton Rose Fulbright US LLP, counsel for Plaintiff.

Adam Edward Szymanski, Esq., Erin H. Chadwick, Esq., and Sarah M. Stensland, Esq., Patterson Thuente Pederson, PA; and James Thomas Wilcox, Esq., and Scott Lloyd Smith, Esq., Buchanan Ingersoll & Rooney PC, counsel for Defendant.

INTRODUCTION

This matter is before the Court on a Motion to Dismiss brought by Defendant ANI Pharmaceuticals, Inc. (Doc. No. 14.) For the reasons set forth below, the Court grants the motion insofar as Defendant seeks dismissal of Plaintiff's common law unfair competition claim and denies the motion in all other respects.

BACKGROUND

Plaintiff Arbor Pharmaceuticals, LLC, researches, develops, and manufactures prescription drug products. In particular, Plaintiff markets prescription erythromycin ethylsuccinate for oral suspension under the brand names EryPed® and E.E.S.®

Granules, both of which are approved by the U.S. Food and Drug Administration ("FDA"). (Doc. No. 1, Compl. ¶ 2.) EryPed® and E.E.S.® Granules are prescription-only antibiotics. (*Id*. ¶ 11.) According to the Complaint, these products are the only FDA-approved products of their kind on the market. (*Id*. ¶ 14.)

On or around September 2016, Defendant announced the launch of its own Erythromycin Ethylsuccinate for Oral Suspension product (the "Product" or "Defendant's Product"), claiming it to be a generic version of EryPed® and E.E.S.®. (*Id*. ¶¶ 17-18.) Plaintiff alleges that Defendant promotes its Product as FDA-approved and AB-rated pursuant to an approved Abbreviated New Drug Application ("ANDA"). (*Id*. ¶ 27.) Plaintiff further alleges that these promotions are false and misleading because Defendant's Product is not FDA-approved, does not have an AB-rating, and that Defendant does not have a current, approved ANDA for its Product. (*Id*. ¶¶ 29, 30.) Instead, Plaintiff alleges, on information and belief, that Defendant acquired an ANDA from another pharmaceutical company for a discontinued product that had been manufactured using a process that differs from that used by Defendant. (*Id*. ¶ 30.) Plaintiff further alleges that the FDA considers this ANDA to be discontinued and that in December 2016, notified Defendant that its application in connection with its Product was not approvable. (*Id.* ¶ 32.)

Defendant acknowledges that it purchased the ANDA and took steps to market its Product as a generic to EryPed® and E.E.S.® Granules. Defendant submits that the relevant ANDA was originally approved in 1978 for Barr Pharmaceuticals, that Barr

stopped marketing the approved product in 2003, and that the ANDA was discontinued. (Doc. No. 16 at 3.) Defendant also represents that on August 26, 2016, it filed a supplement to the ANDA with the FDA, detailing changes it made to the manufacturing process of the Product. Defendant indicated its intent to market the Product if the FDA did not advise otherwise within 30 days. Having not received an objection from the FDA within that period, Defendant now contends that the FDA is aware that it is distributing its Product and has not asked Defendant to stop. (Doc. No. 16 at 5.)[1]

In this action, Plaintiff asserts the following claims: False Advertising in Violation of the Lanham Act (Count I); Unfair Competition in Violation of the Lanham Act (Count II); Common Law Unfair Competition (Count III); Violation of the Minnesota Unfair Trade Practices Act (Count IV); Violation of the Minnesota Uniform Deceptive Trade Practices Act (Count V); and Violation of the Minnesota False Advertising Act (Count VI). (Compl.) At the heart of all of Plaintiff's claims is the assertion that Defendant is falsely advertising its Product as an FDA-approved, AB-rated, generic substitute for EryPed® and E.E.S.® Granules. Defendant moves to dismiss all of Plaintiff's claims with prejudice.

[1] Defendant submits much of the above information in its briefing without citation to the Complaint or documents embraced therein.

DISCUSSION

I. Legal Standard

In deciding a motion to dismiss under Rule 12(b)(6), a court assumes all facts in the complaint to be true and construes all reasonable inferences from those facts in the light most favorable to the complainant. *Morton v. Becker*, 793 F.2d 185, 187 (8th Cir. 1986). In doing so, however, a court need not accept as true wholly conclusory allegations, *Hanten v. Sch. Dist. of Riverview Gardens*, 183 F.3d 799, 805 (8th Cir. 1999), or legal conclusions drawn by the pleader from the facts alleged, *Westcott v. City of Omaha*, 901 F.2d 1486, 1488 (8th Cir. 1990). A court deciding a motion to dismiss may consider the complaint, matters of public record, orders, materials embraced by the complaint, and exhibits attached to the complaint. *See Porous Media Corp. v. Pall Corp.*, 186 F.3d 1077, 1079 (8th Cir. 1999).

To survive a motion to dismiss, a complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Although a complaint need not contain "detailed factual allegations," it must contain facts with enough specificity "to raise a right to relief above the speculative level." *Id*. at 555. As the Supreme Court reiterated, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements," will not pass muster under *Twombly*. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 555). In sum, this standard "calls for enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of [the claim]." *Twombly*, 550 U.S. at 556.

II. The FDCA and FDA

The primary regulatory system governing prescription drugs was created by the Food, Drug and Cosmetic Act ("FDCA"). 21 U.S.C. §§ 301, *et al*. To implement the FDCA, the FDA has promulgated rules and regulations regarding drug labeling. The FDCA requires FDA approval, through a new drug application ("NDA"), before a new drug may enter the market. *Id*. § 355(a). A product similar to an NDA-approved drug may be approved and marketed based on an ANDA, which requires the manufacturer of the similar drug to demonstrate that the two drugs are therapeutically equivalent. *Id*. at § 355(j)(2)(A)(i)-(viii). If the FDA determines that a Reference Listed Drug and the ANDA product are therapeutically equivalent, it gives the ANDA product an AB-rating. (Compl. ¶ 13.) An AB-rating communicates that the product is a true generic. (*Id*.)

III. Defendant's Motion

A. Lanham Act Claims

In Counts I and II, Plaintiff asserts Lanham Act claims based on the allegations of false and deceptive advertising. Section 43(a) of the Lanham Act provides a cause of action when "[a]ny person," in connection with any good or services, uses in commerce "any word" or "misleading description of fact" which "in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods." 15 U.S.C. §1125(a)(1)(B). The Lanham Act is intended "to protect persons engaged in [] commerce against unfair competition." *Lexmark Int'l, Inc. v. Static Control Components, Inc*., 134 S. Ct. 1377, 1389 (2014)

(quoting 15 U.S.C. § 1127). To establish a Lanham Act claim, a plaintiff must demonstrate that: (1) the defendant made a false statement of fact in a commercial advertisement about its own or another's product; (2) the statement actually deceived or has the tendency to deceive a substantial segment of its audience; (3) the deception is material; (4) the defendant caused its false statement to enter into interstate commerce; and (5) plaintiff has been or is likely to be injured as a result of the false statement. *United Indus. Corp. v. Clorox Co*., 140 F.3d 1175, 1180 (8th Cir. 1998). The false statement normally falls into one of two categories: (1) commercial claims that are literally false as a factual matter; and (2) claims that may be literally true or ambiguous but which implicitly convey a false impression, are misleading in context, or are likely to deceive consumers. *Id*. (citation omitted).

Defendant argues that Plaintiff's allegations of a Lanham Act violation are bald and conclusory and therefore do not satisfy *Iqbal* and *Twombly*. Defendant's argument is brief and made as a final argument for dismissal. Nonetheless, the Court dispenses with the argument at the outset and determines that Plaintiff's pleading is sufficient. In its Complaint, Plaintiff alleges that its EryPed® and E.E.S.® Granules are the only FDA-approved products of their kind on the market, and that Defendant launched an unapproved product. (Compl. ¶¶ 12-28.) Plaintiff further claims that Defendant makes three literally false claims when promoting its Product, namely that the Product is: (1) a generic equivalent to EryPed® and E.S.C.® Granules; (2) AB-rated; and (3) FDA-approved. Plaintiff also alleges in the Complaint that these statements are deceptive and

material, that Defendant's Product is advertised in interstate commerce, that Defendant intended to succeed in taking sales away from Plaintiff. (Compl. ¶¶ 17, 34, 35, 48.) Plaintiff further alleges that Defendant's advertising is false and misleading because the ANDA that it acquired is discontinued and therefore cannot be relied upon to support Defendant's marketing claims. (*Id*. ¶¶ 29-33.) These allegations are sufficient to state claims under the Lanham Act.[2]

Defendant's primary argument for the dismissal of Plaintiff's Lanham Act claims is that they are precluded under the FDCA. Specifically, Defendant argues that any determination on the Lanham Act claims (namely, the falsity of Defendant's promotions) would require the Court interpret and apply the FDCA. The primary case relevant to this argument, which is discussed at length by both parties, is *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2233 (2014). In *POM*, the maker of juice products sued its competitor under the Lanham Act for the use of an allegedly deceptive and misleading label on a juice product—namely a label with a prominent display of "pomegranate blueberry" when the product contained only small amounts of pomegranate and blueberry juice. *Id*. at 2233. The question before the Supreme Court was whether a private party may bring a Lanham Act claim challenging a food label that is regulated by the FDCA. *Id*. at 2236. The Supreme Court considered the intersection of the Lanham Act and the

[2] Similarly, Plaintiff's claims under the Minnesota Unlawful Trade Practices Act (Count IV), Minnesota Deceptive Trade Practices Act (Count V), and Minnesota False Advertising (Count VI), are sufficiently pled. *See LensCrafters, Inc. v. Vision World, Inc.*, 943 F. Supp. 1481, 1488 (D. Minn. 1996) (applying Lanham Act analysis to state-law claims).

FDCA, noting that the Lanham Act creates a private right of action for competitors to protect against unfair competition through misleading advertising and that the FDCA statutory regime is designed primarily to protect the health and safety of the public and does not provide a private right of action. *Id*. at 2230, 2234. The Supreme Court explained that "Congress intended the Lanham Act and the FDCA to complement each other with respect to food and beverage labeling" and declined to "elevate the FDCA and the FDA's regulations over the private cause of action authorized by the Lanham Act." *Id*. at 2240-41. Accordingly, the Supreme Court held that the FDA's exclusive enforcement authority over the FDCA did not preclude a Lanham Act claim for false advertising involving FDA-regulated labeling. *Id*. at 2233 & 2237 (explaining that FDCA-regulated labeling is not "under the terms of either statute, off limits to Lanham Act claims"). It is worth noting, however, the Supreme Court appears to have left open the possibility that certain Lanham Act claims could be precluded by the FDCA:

> Unlike other types of labels regulated by the FDA, such as drug labels, *see* 21 U.S.C. § 355(d), it would appear the FDA does not preapprove food and beverage labels under its regulations and instead relies on enforcement actions, warning letters, and other measures.

Id. at 2239. At least one court has indicated that the above passage suggests, "at a minimum, that the Court might find a Lanham Act claim precluded by the FDCA where it turns on the content of a drug label, especially if that drug label were preapproved by the FDA." *JHP Pharm., LLC v. Hospira, Inc.*, 52 F. Supp. 3d 992, 998 (C.D. Cal. 2014).

Defendant argues that *POM* does not apply to this case and that courts have continued to find preclusion where a plaintiff's claims would require the Court to

interpret and apply the FDCA. *See, e.g., Church & Dwight Co. Inc. v. SPD Swiss Precision Diagnostics, GmbH*, 104 F. Supp. 3d 348, 361 (S.D.N.Y. 2015) (finding a Lanham Act claim is not precluded, but agreeing with "the longstanding proposition that private parties may not use the Lanham Act as a vehicle to enforce the FDCA"); *Catheter Connections, Inc. v. Ivera Med. Corp.*, Civ. No. 14-70, 2014 WL 3536573, at *4-6 (D. Utah July 17, 2014) (finding a Lanham Act claim regarding advertisements of a medical device as "FDA approved" precluded where a determination of such approval is within the agency's purview). The Court acknowledges that there are cases where a party's Lanham Act claims are properly precluded under the FDCA, but finds that this is not such a case.

Here, Plaintiff asserts an injury as a competitor and seeks to enforce the Lanham Act, not the FDCA or the FDA regulations. Courts construing *POM* have found that false advertising claims based on false representations of FDA approval are not precluded. For example, in *JHP Pharm., LLC v. Hospira, Inc.*, the manufacturer of injectable epinephrine brought Lanham Act claims against defendant manufacturers for selling injectable epinephrine products that are not FDA-approved while representing that they are so approved. 52 F. Supp. 3d at 1000. In *JHP*, the court explained that false representations that a drug is approved "undermine the Lanham Act's public policy goals both by confusing consumers and by enabling unfair competition." *Id*. After considering the impact of *POM* on the law of preclusion with regard to Lanham Act cases and the FDCA, the court held that the Lanham Act claims were not precluded. *Id*. at 1001. In

JHP, the defendants did not deny that their products were not FDA-approved, a fact the Court found pertinent in determining that the claim was not precluded. *Id*. (noting the case was "very different" than one where a manufacturer could plausibly claim that its product was approved until and unless the FDA determined otherwise).

In this case, Defendant argues that it owns an ANDA for its Product and that Plaintiff cannot circumvent the FDA's regulatory and enforcement authority by seeking to assert that its Product is not FDA-approved. Defendant also argues that the FDA is aware that it is distributing its Product, has not instructed it to cease distribution, and therefore tacitly approves of the ANDA while it considers Defendant's supplement. Defendant, however, does not rely on any pleaded facts in support of these contentions and, instead, simply recites them in its brief. Plaintiff, however, alleges in the Complaint that the FDA considers the ANDA to be discontinued and that Defendant was notified of this in December 2016. Moreover, the FDA maintains a list of approved generics at https://www.fda.gov/downloads/Drugs/ResourcesforYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/UCM564441.pdf, and as of the latest printing on June 29, 2018, the list does not include Defendant's Product.[3] Because Plaintiff alleges that Defendant is promoting its product as a generic equivalent when the facts, as alleged, demonstrate that it is not listed as a generic equivalent, the Court is not

[3] The Court takes judicial notice of the information contained on the FDA website. *See, e.g.*, *Missourians for Fiscal Responsibility v. Klahr*, 830 F.3d 789, 793 (8th Cir. 2016) (recognizing authority to take judicial notice of government websites).

required to interpret or apply the FDCA in determining whether the statements are false. In addition, any determination of falsity lies outside of the expertise and authority of the FDA. Accordingly, the Court concludes that Plaintiff's Lanham Act claims are not precluded.

B. Primary Jurisdiction Doctrine

Defendant also argues that this case should be dismissed under the doctrine of primary jurisdiction. The doctrine of primary jurisdiction "applies where a claim is originally cognizable in the courts, and comes into play whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body." *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 938 (8th Cir. 2005) (citation omitted). The applicability of the doctrine is not governed by a fixed formula and any given case depends on "whether the reasons for the existence of the doctrine are present and whether the purposes it serves will be aided by its application." *Id*. (citation omitted). Such reasons include the promotion of consistency and uniformity within the areas of regulation and the use of agency expertise. *Id.* Defendant argues that deference to the FDA is appropriate here because it is currently engaged with the FDA concerning its supplement to the ANDA and the FDA has allowed Defendant to continue to market its Product during the regulatory review process.

For the same reasons discussed above with respect to preclusion, the Court rejects Defendant's argument that primary jurisdiction is a bar to Plaintiff's claims. As

explained above, Plaintiff's allegations do not require the Court to interpret or apply the FDCA, and any determination of whether Defendants' statements are false lies outside of the expertise and authority of the FDA. *See, e.g.*, *JHP Pharms*, 52 F. Supp. 3d at 1002 (explaining that there is no need to invoke the primary jurisdiction doctrine where it takes no special expertise to determine whether the FDA has granted approval or not).

C. State and Common-Law Claims

Plaintiff also asserts state-law claims under the Minnesota Unfair Trade Practices Act, Minnesota Uniform Deceptive Trade Practices Act, Minnesota False Advertising Act, and for common law unfair competition. Defendant argues that these claims are preempted by the FDCA because each of Plaintiff's state-law claims would require the Court to interpret and apply the FDCA. Again, for the reasons discussed above, the Court need not interpret or apply the FDCA or FDA regulations in order to determine whether Defendants' statements are false. Therefore, these claims are not preempted.

Finally, Defendant moves to dismiss Plaintiff's claim of common law unfair competition (Count III), arguing that it is merely duplicative of other claims in the case. "Unfair competition is not a tort with specific elements; it describes a general category of torts which courts recognize for the protection of commercial interests" including "product disparagement," "tortious interference with contractual interests and improper use of trade secrets." *Zimmerman Grp., Inc. v. Fairmont Foods of Minn., Inc.*, 882 F. Supp. 892, 895 (D. Minn. 1994) (internal quotation marks omitted). "[T]o remain viable, a common law unfair competition claim 'must identify the underlying tort which

is the basis for the claim.'" *LensCrafters, Inc.*, 943 F. Supp. at 1490 (D. Minn. 1996) (alteration and citation omitted). In addition, where an unfair competition claim is duplicative of another claim, the unfair competition claim should be dismissed. *See Zimmerman Grp., Inc.*, 882 F. Supp. at 895.

Plaintiff argues that, despite some common underlying factual allegations, its unfair competition claim is not duplicative of its false advertising claims under the Lanham Act and Minnesota law. Specifically, Plaintiff argues that the nature of alleged injury extends not only to Plaintiff's use of false advertising, but also impacts Plaintiff's reputation insofar as the advertising sows confusion in the market and impacts the market's perception of Plaintiff's own products. (Compl. ¶ 58.) Plaintiff submits, therefore, that Defendant's tortious conduct caused injury beyond lost sales in the form of reputational damage. However, Plaintiff has not identified a tort separate from the false advertising claims upon which it bases the unfair competition claim. The Court determines that the claim is properly dismissed without prejudice.

CONCLUSION

Accepting the facts alleged in the Complaint as true, Plaintiff has stated a claim that Defendant is liable under the Lanham Act and Minnesota law for making false and misleading statements about the approval, rating, and generic equivalence of its Product. With the exception of Plaintiff's common law unfair competition claim, Defendant's motion to dismiss is properly denied.

ORDER

Based on the files, records, and proceedings herein, and for the reasons stated above, **IT IS HEREBY ORDERED** that Defendant's Motion to Dismiss (Doc. No. [14]) is **GRANTED IN PART** and **DENIED IN PART** as follows: Count III is **DISMISSED WITHOUT PREJUDICE**.

Dated: August 2, 2018

s/Donovan W. Frank
DONOVAN W. FRANK
United States District Judge