IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 24-505-JLH
	)	
MSN PHARMACEUTICALS, INC., MSN LABORATORIES PRIVATE LIMITED, AMNEAL PHARMACEUTICALS, INC. and IMPAX LABORATORIES, LLC,	)	
	)	
Defendants.	)	

ORDER

At Wilmington, this 19th day of September 2025,

WHEREAS, on April 23, 2024, Plaintiff Vanda Pharmaceuticals, Inc. ("Plaintiff") filed its Complaint in the above-captioned action against Defendants MSN Pharmaceuticals, Inc., MSN Laboratories Private Limited, Amneal Pharmaceuticals, Inc., and Impax Laboratories LLC ("Defendants") (D.I. 2);

WHEREAS, Count I of the Complaint asserts "False Advertising" in violation of § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and alleges that Defendants are engaged in false or misleading advertising by (1) stating on Amneal's website that Plaintiff's Hetlioz drug is the "Brand Reference" for Defendants' generic product; and (2) listing false data on Amneal's generic product label regarding the mean-elimination half-life and peak concentration for Hetlioz and the generic product;

WHEREAS, there is no real dispute that Plaintiff's Hetlioz drug is in fact the reference listed drug for which Defendants' Abbreviated New Drug Application ("ANDA") sought approval to market a generic version, *see* 21 C.F.R. §§ 314.3, 314.94(a)(3)(i), and Count I is premised

entirely on Plaintiff's assertion that Defendants' ANDA contained falsified and/or flawed bioequivalence data;

WHEREAS, Counts II–VI of the Complaint are state-law claims;

WHEREAS, before filing this action, Plaintiff filed a Citizen Petition at United States Food and Drug Administration ("FDA") (No. FDA-2023-P-1985) and sued FDA in a different federal court (C.A. No. 23-2812 (D.D.C.)) seeking to revoke FDA's approval of the ANDA based on the same alleged flaws in the bioequivalence data that was submitted to FDA in the ANDA;

WHEREAS, on July 31, 2024, Defendants moved to dismiss the Complaint here pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6) or, alternatively, to stay this case pending resolution of Plaintiff's actions involving FDA (D.I. 24);

WHEREAS, on June 30, 2025, FDA denied Plaintiff's Citizen Petition and rejected Plaintiff's assertions about alleged flaws in the bioequivalence data (D.I. 38, Ex. 1);

WHEREAS, on July 30, 2025, Defendants told the Court that their request for a stay was "moot" in view of FDA's denial of Plaintiff's Citizen Petition (D.I. 38);

WHEREAS, on July 31, 2025, Magistrate Judge Burke issued a Report and Recommendation, recommending that the Court (i) grant Defendants' motion to dismiss insofar as it requested dismissal of Count I for failure to state a claim and (ii) decline to exercise jurisdiction of the state-law claims in Counts II–VI (D.I. 39 ("R&R"));

WHEREAS, on August 14, 2025, Plaintiff filed Objections to the R&R, arguing that Judge Burke erred in concluding that Count I did not plausibly state a claim for false advertising under the Lanham Act (D.I. 45);

WHEREAS, on August 28, 2025, Defendants responded to the Objections (D.I. 50);

WHEREAS, the Court has considered the Objections de novo, *see* 28 U.S.C. § 636(b)(1);

WHEREAS, having reviewed the issue de novo, the Court concludes that the R&R should be adopted for the reasons stated by Judge Burke;

NOW, THEREFORE, IT IS HEREBY ORDERED that Plaintiff's Objections to the R&R (D.I. 45) are OVERRULED, the R&R issued on July 31, 2025 (D.I. 39) is ADOPTED, and Defendants' motion to dismiss (D.I. 24) is GRANTED.

1. The Court agrees with Judge Burke that Plaintiff's Lanham Act claim is precluded because it is premised on Plaintiff's assertion that FDA should not have approved Defendants' ANDA—including the content of the label—because it contains allegedly flawed bioequivalence data and therefore does not demonstrate bioequivalence. For the reasons stated by Judge Burke, the Court is unpersuaded that *POM Wonderful LLC v. Coca-Cola Co*., 573 U.S. 102 (2014) permits Plaintiff to maintain a Lanham Act claim under these circumstances. (D.I. 39 at 10–22 (citing *POM Wonderful*, 573 U.S. at 105, 116 (permitting Lanham Act claim for deceptive label on "pomegranate blueberry" juice blend, explaining that juice labels are "not preapprove[d]" by FDA like drug labels)).)

2. Further, as Judge Burke explained, the R&R is in accord with other district courts that have concluded that, even after *POM Wonderful*, Lanham Act claims are precluded to the extent that they challenge enforcement determinations made by FDA pursuant to its exclusive authority under the Federal Food, Drug, and Cosmetic Act (FDCA), or to the extent that they challenge FDA decisions where the agency has taken positive regulatory action. (D.I. 39 at 13–14 (citing cases).) Plaintiff cites several cases that were not presented to Judge Burke for his consideration, but all of them are distinguishable and some even undermine Plaintiff's position. *See, e.g.*, *Eli Lilly & Co. v. Alderwood Surgical Ctr. LLC*, No. 24-878-LK, 2025 WL 745670, at *2, 7 (W.D. Wash. Mar. 7, 2025) (drug products at issue did not go through FDA approval

process); *Gilead Scis., Inc. v. Meritain Health, Inc.*, No. 24-3566, 2025 WL 1745669, at *27 (D. Md. June 24, 2025) (FDCA does not bar or preempt recovery under the Lanham Act "simply because the claim . . . is founded on allegations of conduct also prohibited by the FDCA, *provided adjudication of the Lanham Act claim does not require interpretation or application of the FDCA*" (emphasis added)). Count I is DISMISSED for failure to state a claim.

3. Plaintiff has not argued that the Court should retain jurisdiction over the state claims in Counts II–VI if the Lanham Act claim in Court I is dismissed. Accordingly, the Court agrees with Judge Burke that the Court should decline jurisdiction over Counts II–VI. Counts II–VI are DISMISSED without prejudice.

September 19, 2025

The Honorable Jennifer L. Hall
UNITED STATES DISTRICT JUDGE