IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

OXFORD PHARMACEUTICALS, LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. _____
	)	
THE ALABAMA STATE BOARD OF PHARMACY; CHRIS PHUNG, in his official capacity as President of the Alabama State Board of Pharmacy; ROB COLBURN, in his official capacity as Vice President of the Alabama State Board of Pharmacy; CHRISTY K. GARMON, in her official capacity as Treasurer of the Alabama State Board of Pharmacy; GARY MOUNT, in his official capacity as member of the Alabama State Board of Pharmacy; THOMAS COBB, in his official capacity as member of the Alabama State Board of Pharmacy; DONNA C. YEATMAN, in her official capacity as Executive Secretary of the Alabama State Board of Pharmacy; and the UNITED STATES FOOD AND DRUG ADMINISTRATION,	)	
	)	
Defendants.	)	

COMPLAINT

Oxford Pharmaceuticals, LLC (Oxford) states the following for its complaint:

INTRODUCTION

1. The Alabama State Board of Pharmacy has filed charges against Oxford (an Alabama-licensed drug manufacturer) seeking to revoke Oxford's Alabama license and assess significant disciplinary penalties against it, based on the Board's claim that Oxford violated the federal Food, Drug, and Cosmetic Act (the Act) when the U.S. Food and Drug Administration made certain observations during a May 2019 inspection of Oxford's facility. After the inspection, however, the FDA concluded that the observations did *not* warrant any regulatory or enforcement action and that Oxford had, in fact, minimally complied with current good manufacturing practice, which is the same as being compliant in FDA parlance. Five months after the FDA's determination, the Board itself inspected Oxford's facility and found it to be fully compliant.

2. Now, more than three years later, the Board has brought these charges against Oxford, and the hearing on the charges is set for August 16, 2022. The Board's Statement of Charges claims that the Board seeks to hold Oxford liable for violating section 501(a)(2) of the Act, *see* 21 U.S.C. § 351(a)(2)(B). After Oxford explained to the Board that only the FDA has authority to enforce the Act, the Board told Oxford that it was really alleging that Oxford violated "USP 797," a non-binding pharmacy policy related to compounding pharmacies. (Oxford is not a compounding pharmacy; it is licensed as manufacturer.) One day after that

explanation from the Board, however, the Board said that it actually was charging that Oxford violated current good manufacturing practice (cGMP), based entirely on the FDA's May 2019 inspection observations—even though no Alabama law applicable to Oxford requires such cGMP compliance, even though the Board itself found Oxford's facility compliant one month after the FDA's inspection, and even though the FDA itself concluded that Oxford was cGMP compliant. Thus, at the end of the day, the Board's charges against Oxford continue to be expressly based on the allegation that Oxford violated section 501(a)(2) of the Act, predicated solely upon the form 483 issued by the FDA following its inspection of Oxford *more than three years ago*.

3. Oxford brings this lawsuit to obtain a declaration that the FDA's findings from the May 2019 inspection do not justify any enforcement or disciplinary action against Oxford, as the FDA concluded. The allegations made by the Board threaten to inflict severe damage on Oxford's reputation, and thereby to cause imminent and irreparable harm to Oxford. In addition, if the Board succeeds and disciplines Oxford at the upcoming August 16 hearing, Oxford (which is licensed in all fifty states) will have to report that discipline in most, if not all, of those states and face potential disciplinary actions from the boards in those states. Such a cascade of events would have a debilitating impact on Oxford's business and severely damage its reputation in the industry. The harm from the Board's

continued pursuit of these baseless charges and its efforts to sanction Oxford is impossible to calculate.

4. Oxford also seeks a declaration that the Board does not have authority to enforce the Act against it (only the FDA has the authority to enforce the Act) and that Oxford is not subject to an enforcement or disciplinary action under the Act based on the FDA's May 2019 inspection during which Oxford was deemed to be minimally compliant. In addition, Oxford asserts a procedural due process claim based on the Board's continually-changing theories of liability against Oxford. Oxford has no adequate notice of the charges against it. As a result, in addition to compensatory damages and attorneys' fees, Oxford asks the Court to enjoin the upcoming August 16, 2022 hearing on the Board's Statement of Charges unless and until the Board provides adequate notice of the charges to Oxford and ceases its putative attempts to enforce the Act.

5. Oxford has commenced this action to clear its name in light of the baseless charges brought by the Board. Because the FDA has exclusive authority to enforce the applicable provisions of the federal Food, Drug, and Cosmetic Act, the FDA is a necessary party to this declaratory judgment action.

JURISDICTION AND VENUE

6. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 and § 1367.

7. Venue is proper in this District because the acts and transactions occurred here.

PARTIES

8. Oxford is a Delaware limited liability company that manufactures drugs and holds an Alabama manufacturer's license from the Alabama State Board of Pharmacy.

9. The Alabama State Board of Pharmacy is an Alabama state agency.

10. Chris Phung is the President of the Alabama State Board of Pharmacy and a citizen of Alabama.

11. Rob Colburn is the Vice President of the Alabama State Board of Pharmacy and a citizen of Alabama.

12. Christy K. Garmon is the Treasurer of the Alabama State Board of Pharmacy and a citizen of Alabama.

13. Gary Mount is a member of the Alabama State Board of Pharmacy and a citizen of Alabama.

14. Thomas Cobb is a member of the Alabama State Board of Pharmacy and a citizen of Alabama.

15. Donna C. Yeatman is the Executive Secretary for the Alabama State Board of Pharmacy and a citizen of Alabama.

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