IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AERIE PHARMACEUTICALS, INC. and AERIE DISTRIBUTION, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
MICRO LABS LIMITED and MICRO LABS USA, INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Aerie Pharmaceuticals, Inc. and Aerie Distribution, Inc. (collectively hereinafter, "Aerie"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code and for declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201, *et seq*. This action relates to the Abbreviated New Drug Application ("ANDA") submitted by Micro Labs Limited ("MLL") and Micro Labs USA, Inc. ("ML USA") (collectively, "Micro Labs") to the U.S. Food and Drug Administration ("FDA") for approval to engage in the commercial manufacture, use, or sale of netarsudil ophthalmic solution, 0.02%, a generic version of Aerie's RHOPRESSA® (ANDA No. 216972), prior to the expiration of U.S. Patent Nos. 8,394,826 ("the '826 patent"), 10,174,017 ("the '017 patent"), 10,654,844 ("the '844 patent"), 11,028,081 ("the '081 patent"), 9,415,043 ("the '043 patent"), 9,931,336 ("the '336 patent"), 11,185,538 ("the '538 patent"), and 10,588,901 ("the '901 patent").

2. This action also relates to the ANDA submitted by MLL and ML USA to the FDA for approval to engage in the commercial manufacture, use, or sale of netarsudil and latanoprost

ophthalmic solution, 0.02%/0.005%, a generic version of Aerie's ROCKLATAN® (ANDA No. 216971), prior to the expiration of the '826 patent, the '017 patent, the '844 patent, the '081 patent, the '043 patent, the '336 patent, the '538 patent, the '901 patent, U.S. Patent No. 9,993,470 ("the '470 patent"), and U.S. Patent No. 11,197,853 ("the '853 patent").

THE PARTIES

3. Plaintiff Aerie Pharmaceuticals, Inc. is a company organized and existing under the laws of the State of Delaware, having corporate headquarters at 550 Hills Drive, 3rd Floor, Bedminster, New Jersey 07921.

4. Plaintiff Aerie Distribution, Inc. is a company organized and existing under the laws of the State of Delaware, having corporate headquarters at 4301 Emperor Boulevard, Suite 400B, Durham, North Carolina 27703.

5. Aerie is an ophthalmic pharmaceutical company that discovers, develops, manufactures, and markets novel treatments for diseases of the eye with significant unmet need.

6. On information and belief, Defendant MLL is a company organized and existing under the laws of the Republic of India, having a place of business at 31, Race Course Road, Bangalore, India 560 001. On information and belief, MLL is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including ML USA, throughout the United States, including in New Jersey.

7. On information and belief, Defendant ML USA is a company organized and existing under the laws of New Jersey, having a place of business at 106 Allen Road, Suite 102, Basking Ridge, New Jersey 07920. On information and belief, ML USA is in the business of,

among other things, manufacturing and selling generic versions of branded pharmaceutical drugs throughout the United States, including in New Jersey.

8. On information and belief, ML USA is a wholly owned subsidiary of MLL, and is controlled and/or dominated by MLL.

9. On information and belief, MLL and ML USA collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, MLL and ML USA are agents of each other and/or operate in concert as integrated parts of the same business group. On information and belief, MLL and ML USA acted in concert to develop the products that are the subject of Micro Labs' ANDA Nos. 216971 and 216972 and to seek regulatory approval from the FDA to market and sell such products throughout the United States, including in New Jersey.

10. On information and belief, MLL and ML USA intend to act collaboratively to obtain approval for Micro Labs' ANDA Nos. 216971 and 216972, and, in the event the FDA approves those ANDAs, to commercially manufacture, use, offer for sale, sell, and/or import the products that are the subjects of such ANDAs in the United States, including in New Jersey.

11. On information and belief, Micro Labs assembled and caused to be submitted to the FDA ANDA Nos. 216971 and 216972 pursuant to 21 U.S.C. § 355(j) (§ 505(j) of the FDCA) (hereinafter "Micro Labs' ANDAs"). ANDA No. 216791 ("Micro Labs' Netarsudil/Latanoprost ANDA") concerns a proposed drug product, netarsudil and latanoprost ophthalmic solution at eq 0.02% base and 0.005% ("Micro Labs' Proposed Netarsudil/Latanoprost Product"); ANDA No. 216792 ("Micro Labs' Netarsudil ANDA") concerns a proposed drug product, netarsudil ophthalmic solution at eq 0.02% base ("Micro Labs' Proposed Netarsudil Product") (collectively hereinafter "Micro Labs' ANDAs" and "Micro Labs' Proposed ANDA Products"). Micro Labs'

ANDAs refer to and rely upon Aerie's NDA No. 208254 for RHOPRESSA® and NDA No. 208259 for ROCKLATAN®.

12. By letter dated January 31, 2022 ("Micro Labs' Notice Letter"), Micro Labs notified Aerie Pharmaceuticals, Inc. that, as a part of its ANDAs, Micro Labs had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '826 patent, the '017 patent, the '844 patent, the '081 patent, the '043 patent, the '336 patent, the '538 patent, the '901 patent, the '470 patent, and the '853 patent, asserting that the '826 patent, the '017 patent, the '844 patent, the '081 patent, the '043 patent, the '336 patent, the '538 patent, the '901 patent, the '470 patent, and the '853 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Micro Labs' Proposed ANDA Products. The '826 patent, the '017 patent, the '844 patent, the '081 patent, the '043 patent, the '336 patent, the '538 patent, and the '901 patent are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for RHOPRESSA®. The '826 patent, the '017 patent, the '844 patent, the '081 patent, the '043 patent, the '336 patent, the '538 patent, the '901 patent, the '470 patent, and the '853 patent are listed in the Orange Book for ROCKLATAN®.

JURISDICTION AND VENUE

13. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq*., and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

14. This Court has personal jurisdiction over MLL because, *inter alia*, MLL has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, MLL develops,

manufactures, imports, markets, offers to sell, sells, and/or distributes a broad range of generic pharmaceutical products throughout the United States, including in New Jersey, and therefore transacts business within New Jersey relating to Aerie's claims, and/or has engaged in systematic and continuous business contacts within New Jersey.

15. In addition, this Court has personal jurisdiction over MLL because, among other things, on information and belief, (1) MLL and its subsidiary ML USA filed Micro Labs' ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, sale, or offer for sale of Micro Labs' Proposed ANDA Products in the United States, including in New Jersey, and (2) upon approval of Micro Labs' ANDAs, MLL and its subsidiary ML USA will market, distribute, offer for sale, sell, and/or import Micro Labs' Proposed ANDA Products in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Micro Labs' Proposed ANDA Products in New Jersey. On information and belief, upon approval of Micro Labs' ANDAs, Micro Labs' Proposed ANDA Products will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have substantial effects on New Jersey and lead to foreseeable harm and injury to Aerie.

16. In addition, this Court has personal jurisdiction over MLL because it regularly engages in patent litigation concerning Micro Labs' ANDA products in this District, does not contest personal jurisdiction in this District, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.*, *Allergan Sales, LLC et al. v. Micro Labs Ltd. and Micro Labs USA, Inc.*, C.A. No. 19-cv-09759-ES-SCM,

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