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,

D.I. 10 (D.N.J. June 3, 2019); *Takeda GmbH et al. v. Micro Labs USA, Inc. and Micro Labs Ltd.*, C.A. No. 15-cv-07921-FLW-DEA, D.I. 7 (D.N.J. Nov. 18, 2015).

17. In the alternative, MLL is subject to jurisdiction throughout the United States, and specifically in the State of New Jersey pursuant to Fed. R. Civ. P. 4(k)(2).

18. This Court has personal jurisdiction over ML USA because, on information and belief, ML USA is a company organized and existing under the laws of New Jersey and is qualified to do business in New Jersey. Therefore, ML USA has consented to general jurisdiction in New Jersey.

19. For at least the above reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, it would not be unfair or unreasonable for Micro Labs to litigate this action in this District, and Micro Labs is subject to personal jurisdiction in this District.

20. Venue is proper in this district for MLL under 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, MLL is a corporation existing under the laws of India and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

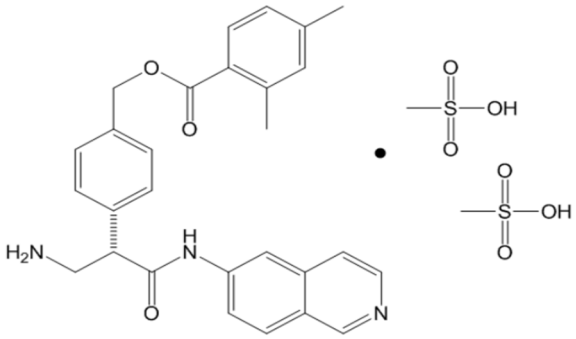
21. Venue is proper in this district for ML USA under 28 U.S.C. § 1400(b) because, *inter alia*, ML USA is a company organized and existing under the laws of the State of New Jersey.

RHOPRESSA®

22. Aerie Pharmaceuticals, Inc. holds approved NDA No. 208254 for netarsudil mesylate solution/drops EQ 0.02% base, which is prescribed and sold in the United States under the trademark RHOPRESSA®. The FDA approved NDA No. 208254 on December 18, 2017.

23. RHOPRESSA® is indicated for the reduction of elevated intraocular pressure ("IOP") in patients with open-angle glaucoma or ocular hypertension.

24. RHOPRESSA® contains netarsudil as a dimesylate salt (netarsudil dimesylate), which can be referred to by the chemical name (S)-4-(3-amino-1-(isoquinolin-6-yl-amino)-1-oxopropan-2-yl) benzyl 2,4-dimethylbenzoate dimesylate and has the following chemical structure:



25. RHOPRESSA® is supplied as a sterile, isotonic, buffered aqueous solution of netarsudil dimesylate. It is intended for topical application in the eye. Each mL of RHOPRESSA® contains 0.2 mg of netarsudil (equivalent to 0.28 mg of netarsudil dimesylate).

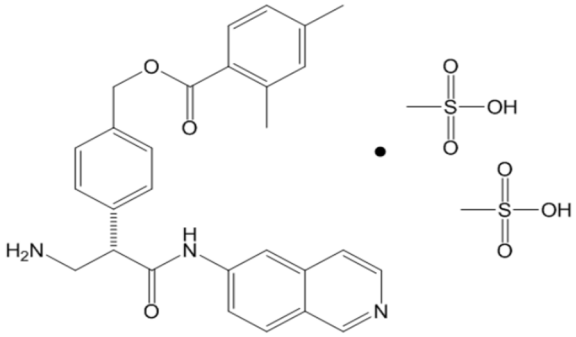
ROCKLATAN®

26. Aerie Pharmaceuticals, Inc. holds approved NDA No. 208259 for latanoprost; netarsudil dimesylate solution/drops 0.005%; EQ 0.02% base, which is prescribed and sold in the United States under the trademark ROCKLATAN®. The FDA approved NDA No. 208259 on March 12, 2019.

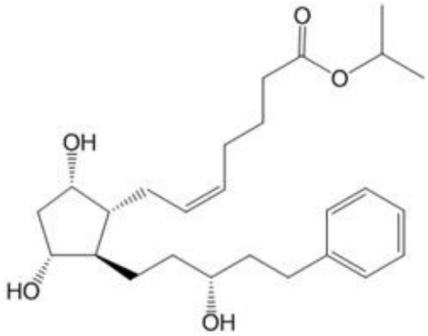
27. ROCKLATAN® is a fixed dose combination of netarsudil (a Rho kinase inhibitor) and latanoprost (a prostaglandin $F_{2\alpha}$ analogue) indicated for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension.

28. ROCKLATAN® contains netarsudil as a dimesylate salt (netarsudil dimesylate), which can be referred to by the chemical name (S)-4-(3-amino-1-(isoquinolin-6-yl-amino)-1-

oxopropan-2-yl) benzyl 2,4-dimethylbenzoate dimesylate and has the following chemical structure:



29. ROCKLATAN® contains latanoprost, which is a prostaglandin $F_{2\alpha}$ analogue and can be referred to by the chemical name isopropyl-(Z)-7[1R,2R,3R,5S) 3,5-dihydroxy-2-[(3R)-3-hydroxy-5-phenylpentyl]cyclopentyl]-5-heptenoate. It has the following chemical structure:



30. ROCKLATAN® is supplied as a sterile, isotonic, buffered aqueous solution of netarsudil mesylate and latanoprost. Each mL of ROCKLATAN® contains 0.2 mg of netarsudil (equivalent to 0.28 mg of netarsudil dimesylate) and 0.05 mg latanoprost.

THE PATENTS-IN-SUIT

31. United States Patent No. 8,394,826 (copy attached as Exhibit A) is entitled "Dual Mechanism Inhibitors for the Treatment of Disease" and was duly and legally issued by the United States Patent and Trademark Office on March 12, 2013. It is owned by Aerie Pharmaceuticals,

Inc. and licensed exclusively to Aerie Distribution, Inc. The '826 patent is directed to, *inter alia*, netarsudil, pharmaceutical compositions containing netarsudil, methods for treating eye disease, including glaucoma or neurodegenerative eye disease, methods of modulating kinase activity, and methods of reducing IOP, including the uses of ROCKLATAN® and RHOPRESSA® in accordance with the labelings approved by the FDA. It is listed in the Orange Book for ROCKLATAN® and RHOPRESSA®.

32. United States Patent No. 10,174,017 (copy attached as Exhibit B) is entitled "Dual Mechanism Inhibitors for the Treatment of Disease" and was duly and legally issued by the United States Patent and Trademark Office on January 8, 2019. It is owned by Aerie Pharmaceuticals, Inc. and licensed exclusively to Aerie Distribution, Inc. The '017 patent is related to the '826 patent through a series of continuation and divisional applications and relies on the same provisional application as the '826 patent. The '017 patent is directed to, *inter alia*, netarsudil, pharmaceutical compositions containing netarsudil, methods for treating eye disease, including glaucoma, neurodegenerative eye disease, or ocular hypertension, methods of modulating kinase activity, and methods of reducing IOP, including the uses of ROCKLATAN® and RHOPRESSA® in accordance with the labelings approved by the FDA. It is listed in the Orange Book for ROCKLATAN® and RHOPRESSA®.

33. United States Patent No. 10,654,844 (copy attached as Exhibit C) is entitled "Dual Mechanism Inhibitors for the Treatment of Disease" and was duly and legally issued by the United States Patent and Trademark Office on May 19, 2020. It is owned by Aerie Pharmaceuticals, Inc. and licensed exclusively to Aerie Distribution, Inc. The '844 patent is related to the '826 patent through a series of continuation and divisional applications and relies on the same provisional application as the '826 and '017 patents. The '844 patent is directed to, *inter alia*, netarsudil,

pharmaceutical compositions containing netarsudil, and methods of treating eye disease, including glaucoma and ocular hypertension, including the uses of ROCKLATAN® and RHOPRESSA® in accordance with the labelings approved by the FDA. It is listed in the Orange Book for ROCKLATAN® and RHOPRESSA®.

34. United States Patent No. 11,028,081 (copy attached as Exhibit D) is entitled "Dual Mechanism Inhibitors for the Treatment of Disease" and was duly and legally issued by the United States Patent and Trademark Office on June 8, 2021. It is owned by Aerie Pharmaceuticals, Inc. and licensed exclusively to Aerie Distribution, Inc. The '081 patent is a continuation of the '844 patent and relies on the same provisional application as the '844, '826, and '017 patents. The '081 patent is directed to, *inter alia*, methods of treating glaucoma or ocular hypertension including the uses of ROCKLATAN® and RHOPRESSA® in accordance with the labelings approved by the FDA. It is listed in the Orange Book for ROCKLATAN® and RHOPRESSA®.

35. United States Patent No. 9,415,043 (copy attached as Exhibit E) is entitled "Combination Therapy" and was duly and legally issued by the United States Patent and Trademark Office on August 16, 2016. It is owned by Aerie Pharmaceuticals, Inc. and licensed exclusively to Aerie Distribution, Inc. The '043 patent is directed to, *inter alia*, netarsudil dimesylate and is listed in the Orange Book for ROCKLATAN® and RHOPRESSA®.

36. United States Patent No. 9,931,336 (copy attached as Exhibit F) is entitled "Combination Therapy" and was duly and legally issued by the United States Patent and Trademark Office on April 3, 2018. It is owned by Aerie Pharmaceuticals, Inc. and licensed exclusively to Aerie Distribution, Inc. The '336 patent is a continuation of the '043 patent and relies on the same provisional patent application. The '336 patent is directed to, *inter alia*, compositions containing netarsudil dimesylate, and methods of treating ocular disorders, including

the uses of ROCKLATAN® and RHOPRESSA® in accordance with the labelings approved by the FDA. It is listed in the Orange Book for ROCKLATAN® and RHOPRESSA®.

37. United States Patent No. 11,185,538 (copy attached as Exhibit G) is entitled "Compositions for Treating Glaucoma or Reducing Intraocular Pressure" and was duly and legally issued by the United States Patent and Trademark Office on November 30, 2021. It is owned by Aerie Pharmaceuticals, Inc. and licensed exclusively to Aerie Distribution, Inc. The '538 patent relates to the '043 and '336 patents through a series of continuation applications and relies on the same provisional patent application as the '043 and '336 patents. The '538 patent is directed to pharmaceutical compositions containing netarsudil dimesylate. It is listed in the Orange Book for ROCKLATAN® and RHOPRESSA®.

38. United States Patent No. 10,588,901 (copy attached as Exhibit H) is entitled "Combination Therapy" and was duly and legally issued by the United States Patent and Trademark Office on March 17, 2020. It is owned by Aerie Pharmaceuticals, Inc. and licensed exclusively to Aerie Distribution, Inc. The '901 patent is a continuation of the '470 patent and relies on the same provisional patent application as the '043, '336, '538, and '470 patents. The '901 patent is directed to, *inter alia*, netarsudil dimesylate, compositions containing netarsudil dimesylate or netarsudil dimesylate and latanoprost, and methods of treating ocular disorders and reducing IOP, including the uses of ROCKLATAN® and RHOPRESSA® in accordance with the labelings approved by the FDA. It is listed in the Orange Book for ROCKLATAN® and RHOPRESSA®.

39. United States Patent No. 9,993,470 (copy attached as Exhibit I) is entitled "Combination Therapy" and was duly and legally issued by the United States Patent and Trademark Office on June 12, 2018. It is owned by Aerie Pharmaceuticals, Inc. and licensed

exclusively to Aerie Distribution, Inc. The '470 patent relies on the same provisional patent application as the '043, '336, '538, and '901 patents. The '470 patent is directed to pharmaceutical compositions containing, *inter alia*, netarsudil dimesylate and latanoprost, and methods of treating ocular disorders, including the use of ROCKLATAN® in accordance with the labeling approved by the FDA. It is listed in the Orange Book for ROCKLATAN®.

40. United States Patent No. 11,197,853 (copy attached as Exhibit J) is entitled "Combination Therapy" and was duly and legally issued by the United States Patent and Trademark Office on December 14, 2021. It is owned by Aerie Pharmaceuticals, Inc. and licensed exclusively to Aerie Distribution, Inc. The '853 patent relates to the '043 and '336 patents through a series of continuation applications and relies on the same provisional patent application as the '043, '336, '538, '901, and '470 patents. The '853 patent is directed to pharmaceutical compositions containing, *inter alia*, netarsudil dimesylate and latanoprost. It is listed in the Orange Book for ROCKLATAN®.

41. The submission of Micro Labs' ANDAs and Micro Labs' intention to commercially manufacture, use, offer for sale, sell, and/or import Micro Labs' Proposed ANDA Products upon receiving FDA approval create an actual case or controversy with respect to infringement 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, the '470 patent, and the '853 patent.

COUNT I: INFRINGEMENT OF
U.S. PATENT NO. 8,394,826 BY MICRO LABS' ANDA NO. 216972

42. Aerie incorporates each of the preceding paragraphs 1 – 41 as if fully set forth herein.

43. On information and belief, Micro Labs submitted ANDA No. 216972 to the FDA under the provisions of 21 U.S.C. § 355(j).

44. Micro Labs, via its Notice Letter, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil Product prior to the expiration of the '826 patent.

45. On information and belief, Micro Labs intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil Product with proposed labeling immediately and imminently upon final approval of its Netarsudil ANDA.

46. On information and belief, Micro Labs made and included in its Netarsudil ANDA a Paragraph IV Certification stating that, in Micro Labs' opinion, the '826 patent is invalid, unenforceable and/or not infringed.

47. By submitting and maintaining its Netarsudil ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sale of its Proposed Netarsudil Product prior to the expiration of the '826 patent, Micro Labs has committed an act of infringement of one or more claims of the '826 patent under 35 U.S.C. § 271(e)(2)(A).

48. Micro Labs' Notice Letter states that Micro Labs' Proposed Netarsudil Product contains (S)-4-(3-amino-1-(isoquinolin-6-yl-amino)-1-oxopropan-2-yl) benzyl 2,4-dimethylbenzoate dimesylate, commonly known as netarsudil dimesylate (a pharmaceutically acceptable salt of netarsudil), and that the dosage form is an ophthalmic solution.

49. Thus, on information and belief, Micro Labs' Proposed Netarsudil Product will directly infringe one or more of the claims of the '826 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

50. On information and belief, Micro Labs' Netarsudil ANDA seeks FDA approval of Micro Labs' Proposed Netarsudil Product for the reduction of elevated IOP in patients with open-

angle glaucoma or ocular hypertension, and the recommended dosage of Micro Labs' Proposed Netarsudil Product will be one drop in the affected eye(s) once daily in the evening.

51. On information and belief, Micro Labs' Proposed Netarsudil Product is especially made or adapted for use in infringing the '826 patent, and Micro Labs' Proposed Netarsudil Product is not suitable for any substantial noninfringing use.

52. Thus, on information and belief, Micro Labs will contribute to the infringement of one or more claims of the '826 patent under 35 U.S.C. § 271(c).

53. On information and belief, Micro Labs' Proposed Netarsudil Product, if approved and marketed, will be accompanied by a product label that will induce physicians to treat ocular (eye) disorders, including glaucoma or neurodegenerative eye disease, reduce IOP, and modulate kinase activity, comprising administering netarsudil dimesylate topically to an eye of the subject, and thereby induce infringement of the methods of one or more claims of the '826 patent under 35 U.S.C. § 271(b).

54. On information and belief, Micro Labs will sell its Proposed Netarsudil Product with instructions encouraging or promoting its use by physicians or patients in a manner that will induce the infringement of one or more claims of the '826 patent under 35 U.S.C. § 271(b).

55. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216972, Micro Labs will make, use, offer to sell, or sell Micro Labs' Proposed Netarsudil Product within the United States, or will import Micro Labs' Proposed Netarsudil Product into the United States, and will thereby infringe, or induce or contribute to infringement of, one or more claims of the '826 patent.

56. On information and belief, Micro Labs has actual knowledge of the '826 patent, as demonstrated by at least Micro Labs' certification 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) described in Micro Labs' Notice Letter, and was aware that the filing of ANDA No. 216972 would constitute an act of infringement of the '826 patent. Micro Labs has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Micro Labs' Proposed Netarsudil Product would not infringe one or more claims of the '826 patent.

57. If Micro Labs' infringement of the '826 patent is not permanently enjoined, Aerie will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II: INFRINGEMENT OF
U.S. PATENT NO. 8,394,826 BY MICRO LABS' ANDA NO. 216971

58. Aerie incorporates each of the preceding paragraphs 1 – 57 as if fully set forth herein.

59. On information and belief, Micro Labs submitted ANDA No. 216971 to the FDA under the provisions of 21 U.S.C. § 355(j).

60. Micro Labs, via its Notice Letter, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil/Latanoprost Product prior to the expiration of the '826 patent.

61. On information and belief, Micro Labs intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil/Latanoprost Product with proposed labeling immediately and imminently upon final approval of its Netarsudil/Latanoprost ANDA.

62. On information and belief, Micro Labs made and included in its Netarsudil/Latanoprost ANDA a Paragraph IV Certification stating that, in Micro Labs' opinion, the '826 patent is invalid, unenforceable and/or not infringed.

63. By submitting and maintaining its Netarsudil/Latanoprost ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sale of its Proposed Netarsudil/Latanoprost Product prior to the expiration of the '826 patent, Micro Labs has committed an act of infringement of one or more claims of the '826 patent under 35 U.S.C. § 271(e)(2)(A).

64. Micro Labs' Notice Letter states that Micro Labs' Proposed Netarsudil/Latanoprost Product contains (S)-4-(3-amino-1-(isoquinolin-6-yl-amino)-1-oxopropan-2-yl) benzyl 2,4-dimethylbenzoate dimesylate, commonly known as netarsudil dimesylate (a pharmaceutically acceptable salt of netarsudil), and isopropyl-(Z)-7[1R,2R,3R,5S) 3,5-dihydroxy-2-[(3R)-3-hydroxy-5-phenylpentyl]cyclopentyl]-5-heptenoate, commonly known as latanoprost, and that the dosage form is an ophthalmic solution.

65. Thus, on information and belief, Micro Labs' Proposed Netarsudil/Latanoprost Product will directly infringe one or more of the claims of the '826 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

66. On information and belief, Micro Labs' Netarsudil/Latanoprost ANDA seeks FDA approval of Micro Labs' Proposed Netarsudil/Latanoprost Product for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension, and the recommended dosage of Micro Labs' Proposed Netarsudil/Latanoprost Product will be one drop in the affected eye(s) once daily in the evening.

67. On information and belief, Micro Labs' Proposed Netarsudil/Latanoprost Product is especially made or adapted for use in infringing the '826 patent, and Micro Labs' Proposed Netarsudil/Latanoprost Product is not suitable for any substantial noninfringing use.

68. Thus, on information and belief, Micro Labs will contribute to the infringement of one or more claims of the '826 patent under 35 U.S.C. § 271(c).

69. On information and belief, Micro Labs' Proposed Netarsudil/Latanoprost Product, if approved and marketed, will be accompanied by a product label that will induce physicians to treat ocular (eye) disorders, including glaucoma or neurodegenerative eye disease, reduce IOP, and modulate kinase activity, comprising administering netarsudil dimesylate topically to an eye of the subject, and thereby induce infringement of the methods of one or more claims of the '826 patent under 35 U.S.C. § 271(b).

70. On information and belief, Micro Labs will sell its Proposed Netarsudil/Latanoprost Product with instructions encouraging or promoting its use by physicians or patients in a manner that will induce the infringement of one or more claims of the '826 patent under 35 U.S.C. § 271(b).

71. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216971, Micro Labs will make, use, offer to sell, or sell Micro Labs' Proposed Netarsudil/Latanoprost Product within the United States, or will import Micro Labs' Proposed Netarsudil/Latanoprost Product into the United States, and will thereby infringe, or induce or contribute to infringement of, one or more claims of the '826 patent.

72. On information and belief, Micro Labs has actual knowledge of the '826 patent, as demonstrated by at least Micro Labs' certification 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) described in Micro Labs' Notice Letter, and was aware that the filing of ANDA No. 216971 would constitute an act of infringement of the '826 patent. Micro Labs has no reasonable basis for asserting that the

commercial manufacture, use, offer for sale, or sale of Micro Labs' Proposed Netarsudil/Latanoprost Product would not infringe one or more claims of the '826 patent.

73. If Micro Labs' infringement of the '826 patent is not permanently enjoined, Aerie will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 10,174,017 BY MICRO LABS' ANDA NO. 216972

74. Aerie incorporates each of the preceding paragraphs 1 – 73 as if fully set forth herein.

75. On information and belief, Micro Labs submitted ANDA No. 216972 to the FDA under the provisions of 21 U.S.C. § 355(j).

76. Micro Labs, via its Notice Letter, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil Product prior to the expiration of the '017 patent.

77. On information and belief, Micro Labs intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil Product with proposed labeling immediately and imminently upon final approval of its ANDA.

78. On information and belief, Micro Labs made and included in its Netarsudil ANDA a Paragraph IV Certification stating that, in Micro Labs' opinion, the '017 patent is invalid, unenforceable and/or not infringed.

79. By submitting and maintaining its Netarsudil ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sale of its Proposed Netarsudil Product prior to the expiration of the '017 patent, Micro Labs has committed an act of infringement of one or more claims of the '017 patent under 35 U.S.C. § 271(e)(2)(A).

80. Micro Labs' Notice Letter states that Micro Labs' Proposed Netarsudil Product contains (S)-4-(3-amino-1-(isoquinolin-6-yl-amino)-1-oxopropan-2-yl) benzyl 2,4-dimethylbenzoate dimesylate, commonly known as netarsudil dimesylate (a pharmaceutically acceptable salt of netarsudil), and that the dosage form is an ophthalmic solution.

81. Thus, on information and belief, Micro Labs' Proposed Netarsudil Product will directly infringe one or more of the claims of the '017 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

82. On information and belief, Micro Labs' Netarsudil ANDA seeks FDA approval of Micro Labs' Proposed Netarsudil Product for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension, and the recommended dosage of Micro Labs' Proposed Netarsudil Product will be one drop in the affected eye(s) once daily in the evening.

83. On information and belief, Micro Labs' Proposed Netarsudil Product is especially made or adapted for use in infringing the '017 patent, and Micro Labs' Proposed Netarsudil Product is not suitable for any substantial noninfringing use.

84. Thus, on information and belief, Micro Labs will contribute to the infringement of one or more claims of the '017 patent under 35 U.S.C. § 271(c).

85. On information and belief, Micro Labs' Proposed Netarsudil Product, if approved and marketed, will be accompanied by a product label that will induce physicians to treat ocular (eye) disorders, including glaucoma, neurodegenerative eye disease, or ocular hypertension, reduce IOP, and modulate kinase activity, comprising administering netarsudil dimesylate topically to an eye of the subject, and thereby induce infringement of the methods of one or more claims of the '017 patent under 35 U.S.C. § 271(b).

86. On information and belief, Micro Labs will sell its Proposed Netarsudil Product with instructions encouraging or promoting its use by physicians or patients in a manner that will induce the infringement of one or more claims of the '017 patent under 35 U.S.C. § 271(b).

87. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216972, Micro Labs will make, use, offer to sell, or sell Micro Labs' Proposed Netarsudil Product within the United States, or will import Micro Labs' Proposed Netarsudil Product into the United States, and will thereby infringe, or induce or contribute to infringement of, one or more claims of the '017 patent.

88. On information and belief, Micro Labs has actual knowledge of the '017 patent, as demonstrated by at least Micro Labs' certification 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) described in Micro Labs' Notice Letter, and was aware that the filing of ANDA No. 216972 would constitute an act of infringement of the '017 patent. Micro Labs has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Micro Labs' Proposed Netarsudil Product would not infringe one or more claims of the '017 patent.

89. If Micro Labs' infringement of the '017 patent is not permanently enjoined, Aerie will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT IV: INFRINGEMENT OF
U.S. PATENT NO. 10,174,017 BY MICRO LABS' ANDA NO. 216971

90. Aerie incorporates each of the preceding paragraphs 1 – 89 as if fully set forth herein.

91. On information and belief, Micro Labs submitted ANDA No. 216971 to the FDA under the provisions of 21 U.S.C. § 355(j).

92. Micro Labs, via its Notice Letter, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil/Latanoprost Product prior to the expiration of the '017 patent.

93. On information and belief, Micro Labs intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil/Latanoprost Product with proposed labeling immediately and imminently upon final approval of its ANDA.

94. On information and belief, Micro Labs made and included in its Netarsudil/Latanoprost ANDA a Paragraph IV Certification stating that, in Micro Labs' opinion, the '017 patent is invalid, unenforceable and/or not infringed.

95. By submitting and maintaining its Netarsudil/Latanoprost ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sale of its Proposed Netarsudil/Latanoprost Product prior to the expiration of the '017 patent, Micro Labs has committed an act of infringement of one or more claims of the '017 patent under 35 U.S.C. § 271(e)(2)(A).

96. Micro Labs' Notice Letter states that Micro Labs' Proposed Netarsudil/Latanoprost Product contains (S)-4-(3-amino-1-(isoquinolin-6-yl-amino)-1-oxopropan-2-yl) benzyl 2,4-dimethylbenzoate dimesylate, commonly known as netarsudil dimesylate (a pharmaceutically acceptable salt of netarsudil), and isopropyl-(Z)-7[1R,2R,3R,5S) 3,5-dihydroxy-2-[(3R)-3-hydroxy-5-phenylpentyl]cyclopentyl]-5-heptenoate, commonly known as latanoprost, and that the dosage form is an ophthalmic solution.

97. Thus, on information and belief, Micro Labs' Proposed Netarsudil/Latanoprost Product will directly infringe one or more of the claims of the '017 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

98. On information and belief, Micro Labs' Netarsudil/Latanoprost ANDA seeks FDA approval of Micro Labs' Proposed Netarsudil/Latanoprost Product for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension, and the recommended dosage of Micro Labs' Proposed Netarsudil/Latanoprost Product will be one drop in the affected eye(s) once daily in the evening.

99. On information and belief, Micro Labs' Proposed Netarsudil/Latanoprost Product is especially made or adapted for use in infringing the '017 patent, and Micro Labs' Proposed Netarsudil/Latanoprost Product is not suitable for any substantial noninfringing use.

100. Thus, on information and belief, Micro Labs will contribute to the infringement of one or more claims of the '017 patent under 35 U.S.C. § 271(c).

101. On information and belief, Micro Labs' Proposed Netarsudil/Latanoprost Product, if approved and marketed, will be accompanied by a product label that will induce physicians to treat ocular (eye) disorders, including glaucoma, neurodegenerative eye disease, or ocular hypertension, reduce IOP, and modulate kinase activity, comprising administering netarsudil dimesylate topically to an eye of the subject, and thereby induce infringement of the methods of one or more claims of the '017 patent under 35 U.S.C. § 271(b).

102. On information and belief, Micro Labs will sell its Proposed Netarsudil/Latanoprost Product with instructions encouraging or promoting its use by physicians or patients in a manner that will induce the infringement of one or more claims of the '017 patent under 35 U.S.C. § 271(b).

103. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216971, Micro Labs will make, use, offer to sell, or sell Micro Labs' Proposed Netarsudil/Latanoprost Product within the United States, or will import Micro Labs' Proposed Netarsudil/Latanoprost Product into the United States, and will thereby infringe, or induce or contribute to infringement of, one or more claims of the '017 patent.

104. On information and belief, Micro Labs has actual knowledge of the '017 patent, as demonstrated by at least Micro Labs' certification 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) described in Micro Labs' Notice Letter, and was aware that the filing of ANDA No. 216971 would constitute an act of infringement of the '017 patent. Micro Labs has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Micro Labs' Proposed Netarsudil/Latanoprost Product would not infringe one or more claims of the '017 patent.

105. If Micro Labs' infringement of the '017 patent is not permanently enjoined, Aerie will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT V: INFRINGEMENT OF
U.S. PATENT NO. 10,654,844 BY MICRO LABS' ANDA NO. 216972

106. Aerie incorporates each of the preceding paragraphs 1 – 105 as if fully set forth herein.

107. On information and belief, Micro Labs submitted ANDA No. 216972 to the FDA under the provisions of 21 U.S.C. § 355(j).

108. Micro Labs, via its Notice Letter, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil Product prior to the expiration of the '844 patent.

109. On information and belief, Micro Labs intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil Product with proposed labeling immediately and imminently upon final approval of its ANDAs.

110. On information and belief, Micro Labs made and included in its Netarsudil ANDA a Paragraph IV Certification stating that, in Micro Labs' opinion, the '844 patent is invalid, unenforceable and/or not infringed.

111. By submitting and maintaining its Netarsudil ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sale of its Proposed Netarsudil Product prior to the expiration of the '844 patent, Micro Labs has committed an act of infringement of one or more claims of the '844 patent under 35 U.S.C. § 271(e)(2)(A).

112. Micro Labs' Notice Letter states that Micro Labs' Proposed Netarsudil Product contains (S)-4-(3-amino-1-(isoquinolin-6-yl-amino)-1-oxopropan-2-yl) benzyl 2,4-dimethylbenzoate dimesylate, commonly known as netarsudil dimesylate (a pharmaceutically acceptable salt of netarsudil), and that the dosage form is an ophthalmic solution.

113. Thus, on information and belief, Micro Labs' Proposed Netarsudil Product will directly infringe one or more of the claims of the '844 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

114. On information and belief, Micro Labs' Netarsudil ANDA seeks FDA approval of Micro Labs' Proposed Netarsudil Product for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension, and the recommended dosage of Micro Labs' Proposed Netarsudil Product will be one drop in the affected eye(s) once daily in the evening.

115. On information and belief, Micro Labs' Proposed Netarsudil Product is especially made or adapted for use in infringing the '844 patent, and Micro Labs' Proposed Netarsudil Product is not suitable for any substantial noninfringing use.

116. Thus, on information and belief, Micro Labs will contribute to the infringement of one or more claims of the '844 patent under 35 U.S.C. § 271(c).

117. On information and belief, Micro Labs' Proposed Netarsudil Product, if approved and marketed, will be accompanied by a product label that will induce physicians to treat ocular (eye) disorders, including glaucoma or ocular hypertension, reduce IOP, and modulate kinase activity, comprising administering netarsudil dimesylate topically to an eye of the subject, and thereby induce infringement of the methods of one or more claims of the '844 patent under 35 U.S.C. § 271(b).

118. On information and belief, Micro Labs will sell its Proposed Netarsudil Product with instructions encouraging or promoting its use by physicians or patients in a manner that will induce the infringement of one or more claims of the '844 patent under 35 U.S.C. § 271(b).

119. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216972, Micro Labs will make, use, offer to sell, or sell Micro Labs' Proposed Netarsudil Product within the United States, or will import Micro Labs' Proposed Netarsudil Product into the United States, and will thereby infringe, or induce or contribute to infringement of, one or more claims of the '844 patent.

120. On information and belief, Micro Labs has actual knowledge of the '844 patent, as demonstrated by at least Micro Labs' certification 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) described in Micro Labs' Notice Letter, and was aware that the filing of ANDA No. 216972 would constitute an act of

infringement of the '844 patent. Micro Labs has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Micro Labs' Proposed Netarsudil Product would not infringe one or more claims of the '844 patent.

121. If Micro Labs' infringement of the '844 patent is not permanently enjoined, Aerie will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VI: INFRINGEMENT OF
U.S. PATENT NO. 10,654,844 BY MICRO LABS' ANDA NO. 216971

122. Aerie incorporates each of the preceding paragraphs 1 – 121 as if fully set forth herein.

123. On information and belief, Micro Labs submitted ANDA No. 216971 to the FDA under the provisions of 21 U.S.C. § 355(j).

124. Micro Labs, via its Notice Letter, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil/Latanoprost Product prior to the expiration of the '844 patent.

125. On information and belief, Micro Labs intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil/Latanoprost Product with proposed labeling immediately and imminently upon final approval of its Netarsudil/Latanoprost ANDA.

126. On information and belief, Micro Labs made and included in its Netarsudil/Latanoprost ANDA a Paragraph IV Certification stating that, in Micro Labs' opinion, the '844 patent is invalid, unenforceable and/or not infringed.

127. By submitting and maintaining its Netarsudil/Latanoprost ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sale of its Proposed Netarsudil/Latanoprost Product prior to the expiration of the '844 patent, Micro Labs

has committed an act of infringement of one or more claims of the '844 patent under 35 U.S.C. § 271(e)(2)(A).

128. Micro Labs' Notice Letter states Micro Labs' Proposed Netarsudil/Latanoprost Product contains (S)-4-(3-amino-1-(isoquinolin-6-yl-amino)-1-oxopropan-2-yl) benzyl 2,4-dimethylbenzoate dimesylate, commonly known as netarsudil dimesylate (a pharmaceutically acceptable salt of netarsudil), and isopropyl-(Z)-7[1R,2R,3R,5S) 3,5-dihydroxy-2-[(3R)-3-hydroxy-5-phenylpentyl]cyclopentyl]-5-heptenoate, commonly known as latanoprost, and that the dosage form is an ophthalmic solution.

129. Thus, on information and belief, Micro Labs' Proposed Netarsudil/Latanoprost Product will directly infringe one or more of the claims of the '844 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

130. On information and belief, Micro Labs' Netarsudil/Latanoprost ANDA seeks FDA approval of Micro Labs' Proposed Netarsudil/Latanoprost Product for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension, and the recommended dosage of Micro Labs' Proposed Netarsudil/Latanoprost Product will be one drop in the affected eye(s) once daily in the evening.

131. On information and belief, Micro Labs' Proposed Netarsudil/Latanoprost Product is especially made or adapted for use in infringing the '844 patent, and Micro Labs' Proposed Netarsudil/Latanoprost Product is not suitable for any substantial noninfringing use.

132. Thus, on information and belief, Micro Labs will contribute to the infringement of one or more claims of the '844 patent under 35 U.S.C. § 271(c).

133. On information and belief, Micro Labs' Proposed Netarsudil/Latanoprost Product, if approved and marketed, will be accompanied by a product label that will induce physicians to

treat ocular (eye) disorders, including glaucoma or ocular hypertension, reduce IOP, and modulate kinase activity, comprising administering netarsudil dimesylate topically to an eye of the subject, and thereby induce infringement of the methods of one or more claims of the '844 patent under 35 U.S.C. § 271(b).

134. On information and belief, Micro Labs will sell its Proposed Netarsudil/Latanoprost Product with instructions encouraging or promoting its use by physicians or patients in a manner that will induce the infringement of one or more claims of the '844 patent under 35 U.S.C. § 271(b).

135. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216971, Micro Labs will make, use, offer to sell, or sell Micro Labs' Proposed Netarsudil/Latanoprost Product within the United States, or will import Micro Labs' Proposed Netarsudil/Latanoprost Product into the United States, and will thereby infringe, or induce or contribute to infringement of, one or more claims of the '844 patent.

136. On information and belief, Micro Labs has actual knowledge of the '844 patent, as demonstrated by at least Micro Labs' certification 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) described in Micro Labs' Notice Letter, and was aware that the filing of ANDA No. 216971 would constitute an act of infringement of the '844 patent. Micro Labs has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Micro Labs' Proposed Netarsudil/Latanoprost Product would not infringe one or more claims of the '844 patent.

137. If Micro Labs' infringement of the '844 patent is not permanently enjoined, Aerie will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VII: INFRINGEMENT OF
U.S. PATENT NO. 11,028,081 BY MICRO LABS' ANDA NO. 216972

138. Aerie incorporates each of the preceding paragraphs 1 – 137 as if fully set forth herein.

139. On information and belief, Micro Labs submitted ANDA No. 216972 to the FDA under the provisions of 21 U.S.C. § 355(j).

140. Micro Labs, via its Notice Letter, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil Product prior to the expiration of the '081 patent.

141. On information and belief, Micro Labs intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil Product with proposed labeling immediately and imminently upon final approval of its Netarsudil ANDA.

142. On information and belief, Micro Labs made and included in its Netarsudil ANDA a Paragraph IV Certification stating that, in Micro Labs' opinion, the '081 patent is invalid, unenforceable and/or not infringed.

143. By submitting and maintaining its Netarsudil ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sale of its Proposed Netarsudil Product prior to the expiration of the '081 patent, Micro Labs has committed an act of infringement of one or more claims of the '081 patent under 35 U.S.C. § 271(e)(2)(A).

144. Micro Labs' Notice Letter states that Micro Labs' Proposed Netarsudil Product contains (S)-4-(3-amino-1-(isoquinolin-6-yl-amino)-1-oxopropan-2-yl) benzyl 2,4-dimethylbenzoate dimesylate, commonly known as netarsudil dimesylate (a pharmaceutically acceptable salt of netarsudil), and that the dosage form is an ophthalmic solution.

145. On information and belief, Micro Labs' Netarsudil ANDA seeks FDA approval of Micro Labs' Proposed Netarsudil Product for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension, and the recommended dosage of Micro Labs' Proposed Netarsudil Product will be one drop in the affected eye(s) once daily in the evening.

146. On information and belief, Micro Labs' Proposed Netarsudil Product is especially made or adapted for use in infringing the '081 patent, and Micro Labs' Proposed Netarsudil Product is not suitable for any substantial noninfringing use.

147. Thus, on information and belief, Micro Labs will contribute to the infringement of one or more claims of the '081 patent under 35 U.S.C. § 271(c).

148. On information and belief, Micro Labs' Proposed Netarsudil Product, if approved and marketed, will be accompanied by a product label that will induce physicians to treat ocular (eye) disorders, including glaucoma or ocular hypertension, comprising administering one drop of netarsudil dimesylate topically to an eye of the subject once daily, and thereby induce infringement of the methods of one or more claims of the '081 patent under 35 U.S.C. § 271(b).

149. On information and belief, Micro Labs will sell its Proposed Netarsudil Product with instructions encouraging or promoting its use by physicians or patients in a manner that will induce the infringement of one or more claims of the '081 patent under 35 U.S.C. § 271(b).

150. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216972, Micro Labs will make, use, offer to sell, or sell Micro Labs' Proposed Netarsudil Product within the United States, or will import Micro Labs' Proposed Netarsudil Product into the United States, and will thereby infringe, or induce or contribute to infringement of, one or more claims of the '081 patent.

151. On information and belief, Micro Labs has actual knowledge of the '081 patent, as demonstrated by at least Micro Labs' certification 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) described in Micro Labs' Notice Letter, and was aware that the filing of ANDA No. 216972 would constitute an act of infringement of the '081 patent. Micro Labs has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Micro Labs' Proposed Netarsudil Product would not infringe one or more claims of the '081 patent.

152. If Micro Labs' infringement of the '081 patent is not permanently enjoined, Aerie will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VIII: INFRINGEMENT OF
U.S. PATENT NO. 11,028,081 BY MICRO LABS' ANDA NO. 216971

153. Aerie incorporates each of the preceding paragraphs 1 – 152 as if fully set forth herein.

154. On information and belief, Micro Labs submitted ANDA No. 216971 to the FDA under the provisions of 21 U.S.C. § 355(j).

155. Micro Labs, via its Notice Letter, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil/Latanoprost Product prior to the expiration of the '081 patent.

156. On information and belief, Micro Labs intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil/Latanoprost Product with proposed labeling immediately and imminently upon final approval of its Netarsudil/Latanoprost ANDA.

157. On information and belief, Micro Labs made and included in its Netarsudil/Latanoprost ANDA a Paragraph IV Certification stating that, in Micro Labs' opinion, the '081 patent is invalid, unenforceable and/or not infringed.

158. By submitting and maintaining its Netarsudil/Latanoprost ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sale of its Proposed Netarsudil/Latanoprost Product prior to the expiration of the '081 patent, Micro Labs has committed an act of infringement of one or more claims of the '081 patent under 35 U.S.C. § 271(e)(2)(A).

159. Micro Labs' Notice Letter states that Micro Labs' Proposed Netarsudil/Latanoprost Product contains (S)-4-(3-amino-1-(isoquinolin-6-yl-amino)-1-oxopropan-2-yl) benzyl 2,4-dimethylbenzoate dimesylate, commonly known as netarsudil dimesylate (a pharmaceutically acceptable salt of netarsudil), and isopropyl-(Z)-7[1R,2R,3R,5S) 3,5-dihydroxy-2-[(3R)-3-hydroxy-5-phenylpentyl]cyclopentyl]-5-heptenoate, commonly known as latanoprost, and that the dosage form is an ophthalmic solution.

160. On information and belief, Micro Labs' Netarsudil/Latanoprost ANDA seeks FDA approval of Micro Labs' Proposed Netarsudil/Latanoprost Product for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension, and the recommended dosage of Micro Labs' Proposed Netarsudil/Latanoprost Product will be one drop in the affected eye(s) once daily in the evening.

161. On information and belief, Micro Labs' Proposed Netarsudil/Latanoprost Product is especially made or adapted for use in infringing the '081 patent, and Micro Labs' Proposed Netarsudil/Latanoprost Product is not suitable for any substantial noninfringing use.

162. Thus, on information and belief, Micro Labs will contribute to the infringement of one or more claims of the '081 patent under 35 U.S.C. § 271(c).

163. On information and belief, Micro Labs' Proposed Netarsudil/Latanoprost Product, if approved and marketed, will be accompanied by a product label that will induce physicians to treat ocular (eye) disorders, including glaucoma or ocular hypertension, comprising administering one drop of netarsudil dimesylate topically to an eye of the subject once daily, and thereby induce infringement of the methods of one or more claims of the '081 patent under 35 U.S.C. § 271(b).

164. On information and belief, Micro Labs will sell its Proposed Netarsudil/Latanoprost Product with instructions encouraging or promoting its use by physicians or patients in a manner that will induce the infringement of one or more claims of the '081 patent under 35 U.S.C. § 271(b).

165. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216971, Micro Labs will make, use, offer to sell, or sell Micro Labs' Proposed Netarsudil/Latanoprost Product within the United States, or will import Micro Labs' Proposed Netarsudil/Latanoprost Product into the United States, and will thereby infringe, or induce or contribute to infringement of, one or more claims of the '081 patent.

166. On information and belief, Micro Labs has actual knowledge of the '081 patent, as demonstrated by at least Micro Labs' certification 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) described in Micro Labs' Notice Letter, and was aware that the filing of ANDA No. 216971 would constitute an act of infringement of the '081 patent. Micro Labs has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Micro Labs' Proposed Netarsudil/Latanoprost Product would not infringe one or more claims of the '081 patent.

167. If Micro Labs' infringement of the '081 patent is not permanently enjoined, Aerie will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT IX: INFRINGEMENT OF
U.S. PATENT NO. 9,415,043 BY MICRO LABS' ANDA NO. 216972

168. Aerie incorporates each of the preceding paragraphs 1 – 167 as if fully set forth herein.

169. On information and belief, Micro Labs submitted ANDA No. 216972 to the FDA under the provisions of 21 U.S.C. § 355(j).

170. Micro Labs, via its Notice Letter, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil Product prior to the expiration of the '043 patent.

171. On information and belief, Micro Labs intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil Product with proposed labeling immediately and imminently upon final approval of its Netarsudil ANDA.

172. On information and belief, Micro Labs made and included in its Netarsudil ANDA a Paragraph IV Certification stating that, in Micro Labs' opinion, the '043 patent is invalid, unenforceable and/or not infringed.

173. By submitting and maintaining its Netarsudil ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sale of its Proposed Netarsudil Product prior to the expiration of the '043 patent, Micro Labs has committed an act of infringement of claim 1, the sole claim, of the '043 patent under 35 U.S.C. § 271(e)(2)(A).

174. Micro Labs' Notice Letter states that Micro Labs' Proposed Netarsudil Product contains (S)-4-(3-amino-1-(isoquinolin-6-yl-amino)-1-oxopropan-2-yl) benzyl 2,4-dimethylbenzoate dimesylate, commonly known as netarsudil dimesylate.

175. Thus, on information and belief, Micro Labs' Proposed Netarsudil Product will directly infringe claim 1, the sole claim, of the '043 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

176. On information and belief, Micro Labs' Proposed Netarsudil Product is especially made or adapted for use in infringing the '043 patent, and Micro Labs' Proposed Netarsudil Product is not suitable for any substantial noninfringing use.

177. Thus, on information and belief, Micro Labs will contribute to the infringement of claim 1, the sole claim, of the '043 patent under 35 U.S.C. § 271(c).

178. On information and belief, Micro Labs will sell its Proposed Netarsudil Product with instructions encouraging or promoting its use by physicians or patients in a manner that will induce the infringement of claim 1, the sole claim, of the '043 patent under 35 U.S.C. § 271(b).

179. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216972, Micro Labs will make, use, offer to sell, or sell Micro Labs' Proposed Netarsudil Product within the United States, or will import Micro Labs' Proposed Netarsudil Product into the United States, and will thereby infringe, or induce or contribute to infringement of, claim 1, the sole claim, of the '043 patent.

180. On information and belief, Micro Labs has actual knowledge of the '043 patent, as demonstrated by at least Micro Labs' certification 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) described in Micro Labs' Notice Letter, and was aware that the filing of ANDA No. 216972 would constitute an act of

infringement of the '043 patent. Micro Labs has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Micro Labs' Proposed Netarsudil Product would not infringe claim 1, the sole claim, of the '043 patent.

181. If Micro Labs' infringement of the '043 patent is not permanently enjoined, Aerie will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT X: INFRINGEMENT OF
U.S. PATENT NO. 9,415,043 BY MICRO LABS' ANDA NO. 216971

182. Aerie incorporates each of the preceding paragraphs 1 – 181 as if fully set forth herein.

183. On information and belief, Micro Labs submitted ANDA No. 216971 to the FDA under the provisions of 21 U.S.C. § 355(j).

184. Micro Labs, via its Notice Letter, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil/Latanoprost Product prior to the expiration of the '043 patent.

185. On information and belief, Micro Labs intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil/Latanoprost Product with proposed labeling immediately and imminently upon final approval of its Netarsudil/Latanoprost ANDA.

186. On information and belief, Micro Labs made and included in its Netarsudil/Latanoprost ANDA a Paragraph IV Certification stating that, in Micro Labs' opinion, the '043 patent is invalid, unenforceable and/or not infringed.

187. By submitting and maintaining its Netarsudil/Latanoprost ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sale of its Proposed Netarsudil/Latanoprost Product prior to the expiration of the '043 patent, Micro Labs

has committed an act of infringement of claim 1, the sole claim, of the '043 patent under 35 U.S.C. § 271(e)(2)(A).

188. Micro Labs' Notice Letter states that Micro Labs' Proposed Netarsudil/Latanoprost Product contains (S)-4-(3-amino-1-(isoquinolin-6-yl-amino)-1-oxopropan-2-yl) benzyl 2,4-dimethylbenzoate dimesylate, commonly known as netarsudil dimesylate (a pharmaceutically acceptable salt of netarsudil), and isopropyl-(Z)-7[1R,2R,3R,5S) 3,5-dihydroxy-2-[(3R)-3-hydroxy-5-phenylpentyl]cyclopentyl]-5-heptenoate, commonly known as latanoprost.

189. Thus, on information and belief, Micro Labs' Proposed Netarsudil/Latanoprost Product will directly infringe claim 1, the sole claim, of the '043 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

190. On information and belief, Micro Labs' Proposed Netarsudil/Latanoprost Product is especially made or adapted for use in infringing the '043 patent, and Micro Labs' Proposed Netarsudil/Latanoprost Product is not suitable for any substantial noninfringing use.

191. Thus, on information and belief, Micro Labs will contribute to the infringement of claim 1, the sole claim, of the '043 patent under 35 U.S.C. § 271(c).

192. On information and belief, Micro Labs will sell its Proposed Netarsudil/Latanoprost Product with instructions encouraging or promoting its use by physicians or patients in a manner that will induce the infringement of claim 1, the sole claim, of the '043 patent under 35 U.S.C. § 271(b).

193. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216971, Micro Labs will make, use, offer to sell, or sell Micro Labs' Proposed Netarsudil/Latanoprost Product within the United States, or will import Micro Labs' Proposed

Netarsudil/Latanoprost Product into the United States, and will thereby infringe, or induce or contribute to infringement of, claim 1, the sole claim, of the '043 patent.

194. On information and belief, Micro Labs has actual knowledge of the '043 patent, as demonstrated by at least Micro Labs' certification 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) described in Micro Labs' Notice Letter, and was aware that the filing of ANDA No. 216971 would constitute an act of infringement of the '043 patent. Micro Labs has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Micro Labs' Proposed Netarsudil/Latanoprost Product would not infringe claim 1, the sole claim, of the '043 patent.

195. If Micro Labs' infringement of the '043 patent is not permanently enjoined, Aerie will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XI: INFRINGEMENT OF
U.S. PATENT NO. 9,931,336 BY MICRO LABS' ANDA NO. 216972

196. Aerie incorporates each of the preceding paragraphs 1 – 195 as if fully set forth herein.

197. On information and belief, Micro Labs submitted ANDA No. 216972 to the FDA under the provisions of 21 U.S.C. § 355(j).

198. Micro Labs, via its Notice Letter, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil Product prior to the expiration of the '336 patent.

199. On information and belief, Micro Labs intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil Product with proposed labeling immediately and imminently upon final approval of its Netarsudil ANDA.

200. On information and belief, Micro Labs made and included in its Netarsudil ANDA a Paragraph IV Certification stating that, in Micro Labs' opinion, the '336 patent is invalid, unenforceable and/or not infringed.

201. By submitting and maintaining its Netarsudil ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sale of its Proposed Netarsudil Product prior to the expiration of the '336 patent, Micro Labs has committed an act of infringement of one or more claims of the '336 patent under 35 U.S.C. § 271(e)(2)(A).

202. Micro Labs' Notice Letter states that Micro Labs' Proposed Netarsudil Product contains (S)-4-(3-amino-1-(isoquinolin-6-yl-amino)-1-oxopropan-2-yl) benzyl 2,4-dimethylbenzoate dimesylate, commonly known as netarsudil dimesylate (a pharmaceutically acceptable salt of netarsudil), and that the dosage form is an ophthalmic solution.

203. Thus, on information and belief, Micro Labs' Proposed Netarsudil Product will directly infringe one or more of the claims of the '336 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

204. On information and belief, Micro Labs' Netarsudil ANDA seeks FDA approval of Micro Labs' Proposed Netarsudil Product for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension, and the recommended dosage of Micro Labs' Proposed Netarsudil Product will be one drop in the affected eye(s) once daily in the evening.

205. On information and belief, Micro Labs' Proposed Netarsudil Product is especially made or adapted for use in infringing the '336 patent, and Micro Labs' Proposed Netarsudil Product is not suitable for any substantial noninfringing use.

206. Thus, on information and belief, Micro Labs will contribute to the infringement of one or more claims of the '336 patent under 35 U.S.C. § 271(c).

207. On information and belief, Micro Labs' Proposed Netarsudil Product, if approved and marketed, will be accompanied by a product label that will induce physicians to treat ocular disorders, including glaucoma, and reduce IOP in subjects in need thereof, comprising administering netarsudil dimesylate topically to an eye of the subject, and thereby induce infringement of the methods of one or more claims of the '336 patent under 35 U.S.C. § 271(b).

208. On information and belief, Micro Labs will sell its Proposed Netarsudil Product with instructions encouraging or promoting its use by physicians or patients in a manner that will induce the infringement of one or more claims of the '336 patent under 35 U.S.C. § 271(b).

209. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216972, Micro Labs will make, use, offer to sell, or sell Micro Labs' Proposed Netarsudil Product within the United States, or will import Micro Labs' Proposed Netarsudil Product into the United States, and will thereby infringe, or induce or contribute to infringement of, one or more claims of the '336 patent.

210. On information and belief, Micro Labs has actual knowledge of the '336 patent, as demonstrated by at least Micro Labs' certification 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) described in Micro Labs' Notice Letter, and was aware that the filing of ANDA No. 216972 would constitute an act of infringement of the '336 patent. Micro Labs has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Micro Labs' Proposed Netarsudil Product would not infringe one or more claims of the '336 patent.

211. If Micro Labs' infringement of the '336 patent is not permanently enjoined, Aerie will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XII: INFRINGEMENT OF
U.S. PATENT NO. 9,931,336 BY MICRO LABS' ANDA NO. 216971

212. Aerie incorporates each of the preceding paragraphs 1 – 211 as if fully set forth herein.

213. On information and belief, Micro Labs submitted ANDA No. 216971 to the FDA under the provisions of 21 U.S.C. § 355(j).

214. Micro Labs, via its Notice Letter, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil/Latanoprost Product prior to the expiration of the '336 patent.

215. On information and belief, Micro Labs intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil/Latanoprost Product with proposed labeling immediately and imminently upon final approval of its Netarsudil/Latanoprost ANDA.

216. On information and belief, Micro Labs made and included in its Netarsudil/Latanoprost ANDA a Paragraph IV Certification stating that, in Micro Labs' opinion, the '336 patent is invalid, unenforceable and/or not infringed.

217. By submitting and maintaining its Netarsudil/Latanoprost ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sale of its Proposed Netarsudil/Latanoprost Product prior to the expiration of the '336 patent, Micro Labs has committed an act of infringement of one or more claims of the '336 patent under 35 U.S.C. § 271(e)(2)(A).

218. Micro Labs' Notice Letter states that Micro Labs' Proposed Netarsudil/Latanoprost Product contains (S)-4-(3-amino-1-(isoquinolin-6-yl-amino)-1-oxopropan-2-yl) benzyl 2,4-dimethylbenzoate dimesylate, commonly known as netarsudil dimesylate (a pharmaceutically

acceptable salt of netarsudil), and isopropyl-(Z)-7[1R,2R,3R,5S) 3,5-dihydroxy-2-[(3R)-3-hydroxy-5-phenylpentyl]cyclopentyl]-5-heptenoate, commonly known as latanoprost, and that the dosage form is an ophthalmic solution.

219. Thus, on information and belief, Micro Labs' Proposed Netarsudil/Latanoprost Product will directly infringe one or more of the claims of the '336 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

220. On information and belief, Micro Labs' Netarsudil/Latanoprost ANDA seeks FDA approval of Micro Labs' Proposed Netarsudil/Latanoprost Product for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension, and the recommended dosage of Micro Labs' Proposed Netarsudil/Latanoprost Product will be one drop in the affected eye(s) once daily in the evening.

221. On information and belief, Micro Labs' Proposed Netarsudil/Latanoprost Product is especially made or adapted for use in infringing the '336 patent, and Micro Labs' Proposed Netarsudil/Latanoprost Product is not suitable for any substantial noninfringing use.

222. Thus, on information and belief, Micro Labs will contribute to the infringement of one or more claims of the '336 patent under 35 U.S.C. § 271(c).

223. On information and belief, Micro Labs' Proposed Netarsudil/Latanoprost Product, if approved and marketed, will be accompanied by a product label that will induce physicians to treat ocular disorders, including glaucoma, and reduce IOP in subjects in need thereof, comprising administering netarsudil dimesylate topically to an eye of the subject, and thereby induce infringement of the methods of one or more claims of the '336 patent under 35 U.S.C. § 271(b).

224. On information and belief, Micro Labs will sell its Proposed Netarsudil/Latanoprost Product with instructions encouraging or promoting its use by physicians

or patients in a manner that will induce the infringement of one or more claims of the '336 patent under 35 U.S.C. § 271(b).

225. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216971, Micro Labs will make, use, offer to sell, or sell Micro Labs' Proposed Netarsudil/Latanoprost Product within the United States, or will import Micro Labs' Proposed Netarsudil/Latanoprost Product into the United States, and will thereby infringe, or induce or contribute to infringement of, one or more claims of the '336 patent.

226. On information and belief, Micro Labs has actual knowledge of the '336 patent, as demonstrated by at least Micro Labs' certification 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) described in Micro Labs' Notice Letter, and was aware that the filing of ANDA No. 216971 would constitute an act of infringement of the '336 patent. Micro Labs has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Micro Labs' Proposed Netarsudil/Latanoprost Product would not infringe one or more claims of the '336 patent.

227. If Micro Labs' infringement of the '336 patent is not permanently enjoined, Aerie will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XIII: INFRINGEMENT OF
U.S. PATENT NO. 11,185,538 BY MICRO LABS' ANDA NO. 216972

228. Aerie incorporates each of the preceding paragraphs 1 – 227 as if fully set forth herein.

229. On information and belief, Micro Labs submitted ANDA No. 216972 to the FDA under the provisions of 21 U.S.C. § 355(j).

230. Micro Labs, via its Notice Letter, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil Product prior to the expiration of the '538 patent.

231. On information and belief, Micro Labs intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil Product with proposed labeling immediately and imminently upon final approval of its Netarsudil ANDA.

232. On information and belief, Micro Labs made and included in its Netarsudil ANDA a Paragraph IV Certification stating that, in Micro Labs' opinion, the '538 patent is invalid, unenforceable and/or not infringed.

233. By submitting and maintaining its Netarsudil ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sale of its Proposed Netarsudil Product prior to the expiration of the '538 patent, Micro Labs has committed an act of infringement of one or more claims of the '538 patent under 35 U.S.C. § 271(e)(2)(A).

234. Micro Labs' Notice Letter states that Micro Labs' Proposed Netarsudil Product contains (S)-4-(3-amino-1-(isoquinolin-6-yl-amino)-1-oxopropan-2-yl) benzyl 2,4-dimethylbenzoate dimesylate, commonly known as netarsudil dimesylate (a pharmaceutically acceptable salt of netarsudil; strength is equivalent to 0.02% of netarsudil base), and that the dosage form is an ophthalmic solution.

235. On information and belief, because Micro Labs' Proposed Netarsudil Product is in the form of an ophthalmic solution, it will be a pharmaceutical composition and will comprise about 0.02% (S)-4-(3-amino-1-(isoquinolin-6-yl-amino)-1-oxopropan-2-yl) benzyl 2,4-

dimethylbenzoate dimesylate (a dimesylate salt) and at least one pharmaceutically acceptable excipient or an equivalent.

236. Thus, on information and belief, Micro Labs' Proposed Netarsudil Product will directly infringe one or more claims of the '538 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

237. On information and belief, Micro Labs' Proposed Netarsudil Product is especially made or adapted for use in infringing the '538 patent, and Micro Labs' Proposed Netarsudil Product is not suitable for any substantial noninfringing use.

238. Thus, on information and belief, Micro Labs will contribute to the infringement of one or more claims of the '538 patent under 35 U.S.C. § 271(c).

239. On information and belief, Micro Labs will sell its Proposed Netarsudil Product with instructions encouraging or promoting its use by physicians or patients in a manner that will induce the infringement of one or more claims of the '538 patent under 35 U.S.C. § 271(b).

240. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216972, Micro Labs will make, use, offer to sell, or sell Micro Labs' Proposed Netarsudil Product within the United States, or will import Micro Labs' Proposed Netarsudil Product into the United States, and will thereby infringe, or induce or contribute to infringement of, one or more claims of the '538 patent.

241. On information and belief, Micro Labs has actual knowledge of the '538 patent, as demonstrated by at least Micro Labs' certification 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) described in Micro Labs' Notice Letter, and was aware that the filing of ANDA No. 216972 would constitute an act of infringement of the '538 patent. Micro Labs has no reasonable basis for asserting that the

commercial manufacture, use, offer for sale, or sale of Micro Labs' Proposed Netarsudil Product would not infringe one or more claims of the '538 patent.

242. If Micro Labs' infringement of the '538 patent is not permanently enjoined, Aerie will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XIV: INFRINGEMENT OF U.S. PATENT NO. 11,185,538 BY MICRO LABS' ANDA NO. 216971

243. Aerie incorporates each of the preceding paragraphs 1 – 242 as if fully set forth herein.

244. On information and belief, Micro Labs submitted ANDA No. 216971 to the FDA under the provisions of 21 U.S.C. § 355(j).

245. Micro Labs, via its Notice Letter, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil/Latanoprost Product prior to the expiration of the '538 patent.

246. On information and belief, Micro Labs intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil/Latanoprost Product with proposed labeling immediately and imminently upon final approval of its Netarsudil/Latanoprost ANDA.

247. On information and belief, Micro Labs made and included in its Netarsudil/Latanoprost ANDA a Paragraph IV Certification stating that, in Micro Labs' opinion, the '538 patent is invalid, unenforceable and/or not infringed.

248. By submitting and maintaining its Netarsudil/Latanoprost ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sale of its Proposed Netarsudil/Latanoprost Product prior to the expiration of the '538 patent, Micro Labs

has committed an act of infringement of one or more claims of the '538 patent under 35 U.S.C. § 271(e)(2)(A).

249. Micro Labs' Notice Letter states that Micro Labs' Proposed Netarsudil/Latanoprost Product contains (S)-4-(3-amino-1-(isoquinolin-6-yl-amino)-1-oxopropan-2-yl) benzyl 2,4-dimethylbenzoate dimesylate, commonly known as netarsudil dimesylate (a pharmaceutically acceptable salt of netarsudil; strength is equivalent to 0.02% of netarsudil base), and isopropyl-(Z)-7[1R,2R,3R,5S) 3,5-dihydroxy-2-[(3R)-3-hydroxy-5-phenylpentyl]cyclopentyl]-5-heptenoate, commonly known as latanoprost (strength is 0.005%), and that the dosage form is an ophthalmic solution.

250. On information and belief, because Micro Labs' Proposed Netarsudil/Latanoprost Product is in the form of an ophthalmic solution, it will be a pharmaceutical composition and will comprise about 0.02% (S)-4-(3-amino-1-(isoquinolin-6-yl-amino)-1-oxopropan-2-yl) benzyl 2,4-dimethylbenzoate dimesylate (a dimesylate salt) and at least one pharmaceutically acceptable excipient or an equivalent.

251. Thus, on information and belief, Micro Labs' Proposed Netarsudil/Latanoprost Product will directly infringe one or more claims of the '538 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

252. On information and belief, Micro Labs' Proposed Netarsudil/Latanoprost Product is especially made or adapted for use in infringing the '538 patent, and Micro Labs' Proposed Netarsudil/Latanoprost Product is not suitable for any substantial noninfringing use.

253. Thus, on information and belief, Micro Labs will contribute to the infringement of one or more claims of the '538 patent under 35 U.S.C. § 271(c).

254. On information and belief, Micro Labs will sell its Proposed Netarsudil/Latanoprost Product with instructions encouraging or promoting its use by physicians or patients in a manner that will induce the infringement of one or more claims of the '538 patent under 35 U.S.C. § 271(b).

255. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216971, Micro Labs will make, use, offer to sell, or sell Micro Labs' Proposed Netarsudil/Latanoprost Product within the United States, or will import Micro Labs' Proposed Netarsudil/Latanoprost Product into the United States, and will thereby infringe, or induce or contribute to infringement of, one or more claims of the '538 patent.

256. On information and belief, Micro Labs has actual knowledge of the '538 patent, as demonstrated by at least Micro Labs' certification 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) described in Micro Labs' Notice Letter, and was aware that the filing of ANDA No. 216971 would constitute an act of infringement of the '538 patent. Micro Labs has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Micro Labs' Proposed Netarsudil/Latanoprost Product would not infringe one or more claims of the '538 patent.

257. If Micro Labs' infringement of the '538 patent is not permanently enjoined, Aerie will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XV: INFRINGEMENT OF
U.S. PATENT NO. 10,588,901 BY MICRO LABS' ANDA NO. 216972

258. Aerie incorporates each of the preceding paragraphs 1 – 257 as if fully set forth herein.

259. On information and belief, Micro Labs submitted ANDA No. 216972 to the FDA under the provisions of 21 U.S.C. § 355(j).

260. Micro Labs, via its Notice Letter, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil Product prior to the expiration of the '901 patent.

261. On information and belief, Micro Labs intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil Product with proposed labeling immediately and imminently upon final approval of its Netarsudil ANDA.

262. On information and belief, Micro Labs made and included in its Netarsudil ANDA a Paragraph IV Certification stating that, in Micro Labs' opinion, the '901 patent is invalid, unenforceable and/or not infringed.

263. By submitting and maintaining its Netarsudil ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sale of its Proposed Netarsudil Product prior to the expiration of the '901 patent, Micro Labs has committed an act of infringement of one or more claims of the '901 patent under 35 U.S.C. § 271(e)(2)(A).

264. Micro Labs' Notice Letter states that Micro Labs' Proposed Netarsudil Product contains (S)-4-(3-amino-1-(isoquinolin-6-yl-amino)-1-oxopropan-2-yl) benzyl 2,4-dimethylbenzoate dimesylate, commonly known as netarsudil dimesylate (a pharmaceutically acceptable salt of netarsudil), and that the dosage form is an ophthalmic solution.

265. Thus, on information and belief, Micro Labs' Proposed Netarsudil Product will directly infringe one or more of the claims of the '901 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

266. On information and belief, Micro Labs' Netarsudil ANDA seeks FDA approval of Micro Labs' Proposed Netarsudil Product for the reduction of elevated IOP in patients with open-

angle glaucoma or ocular hypertension, and the recommended dosage of Micro Labs' Proposed Netarsudil Product will be one drop in the affected eye(s) once daily in the evening.

267. On information and belief, Micro Labs' Proposed Netarsudil Product is especially made or adapted for use in infringing the '901 patent, and Micro Labs' Proposed Netarsudil Product is not suitable for any substantial noninfringing use.

268. Thus, on information and belief, Micro Labs will contribute to the infringement of one or more claims of the '901 patent under 35 U.S.C. § 271(c).

269. On information and belief, Micro Labs' Proposed Netarsudil Product, if approved and marketed, will be accompanied by a product label that will induce physicians to treat ocular disorders, including glaucoma, neurodegenerative eye disease, and ocular hypertension, and reduce IOP in subjects in need thereof, comprising administering netarsudil dimesylate to the subject, and thereby induce infringement of the methods of one or more claims of the '901 patent under 35 U.S.C. § 271(b).

270. On information and belief, Micro Labs will sell its Proposed Netarsudil Product with instructions encouraging or promoting its use by physicians or patients in a manner that will induce the infringement of one or more claims of the '901 patent under 35 U.S.C. § 271(b).

271. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216972, Micro Labs will make, use, offer to sell, or sell Micro Labs' Proposed Netarsudil Product within the United States, or will import Micro Labs' Proposed Netarsudil Product into the United States, and will thereby infringe, or induce or contribute to infringement of, one or more claims of the '901 patent.

272. On information and belief, Micro Labs has actual knowledge of the '901 patent, as demonstrated by at least Micro Labs' certification 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) described in Micro Labs' Notice Letter, and was aware that the filing of ANDA No. 216972 would constitute an act of infringement of the '901 patent. Micro Labs has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Micro Labs' Proposed Netarsudil Product would not infringe one or more claims of the '901 patent.

273. If Micro Labs' infringement of the '901 patent is not permanently enjoined, Aerie will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XVI: INFRINGEMENT OF
U.S. PATENT NO. 10,588,901 BY MICRO LABS' ANDA NO. 216971

274. Aerie incorporates each of the preceding paragraphs 1 – 273 as if fully set forth herein.

275. On information and belief, Micro Labs submitted ANDA No. 216971 to the FDA under the provisions of 21 U.S.C. § 355(j).

276. Micro Labs, via its Notice Letter, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil/Latanoprost Product prior to the expiration of the '901 patent.

277. On information and belief, Micro Labs intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil/Latanoprost Product with proposed labeling immediately and imminently upon final approval of its Netarsudil/Latanoprost ANDA.

278. On information and belief, Micro Labs made and included in its Netarsudil/Latanoprost ANDA a Paragraph IV Certification stating that, in Micro Labs' opinion, the '901 patent is invalid, unenforceable and/or not infringed.

279. By submitting and maintaining its Netarsudil/Latanoprost ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sale of its Proposed Netarsudil/Latanoprost Product prior to the expiration of the '901 patent, Micro Labs has committed an act of infringement of one or more claims of the '901 patent under 35 U.S.C. § 271(e)(2)(A).

280. Micro Labs' Notice Letter states that Micro Labs' Proposed Netarsudil/Latanoprost Product contains (S)-4-(3-amino-1-(isoquinolin-6-yl-amino)-1-oxopropan-2-yl) benzyl 2,4-dimethylbenzoate dimesylate, commonly known as netarsudil dimesylate (a pharmaceutically acceptable salt of netarsudil), and isopropyl-(Z)-7[1R,2R,3R,5S) 3,5-dihydroxy-2-[(3R)-3-hydroxy-5-phenylpentyl]cyclopentyl]-5-heptenoate, commonly known as latanoprost, and that the dosage form is an ophthalmic solution.

281. Thus, on information and belief, Micro Labs' Proposed Netarsudil/Latanoprost Product will directly infringe one or more of the claims of the '901 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

282. On information and belief, Micro Labs' Netarsudil/Latanoprost ANDA seeks FDA approval of Micro Labs' Proposed Netarsudil/Latanoprost Product for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension, and the recommended dosage of Micro Labs' Proposed Netarsudil/Latanoprost Product will be one drop in the affected eye(s) once daily in the evening.

283. On information and belief, Micro Labs' Proposed Netarsudil/Latanoprost Product is especially made or adapted for use in infringing the '901 patent, and Micro Labs' Proposed Netarsudil/Latanoprost Product is not suitable for any substantial noninfringing use.

284. Thus, on information and belief, Micro Labs will contribute to the infringement of one or more claims of the '901 patent under 35 U.S.C. § 271(c).

285. On information and belief, Micro Labs' Proposed Netarsudil/Latanoprost Product, if approved and marketed, will be accompanied by a product label that will induce physicians to treat ocular disorders, including glaucoma, neurodegenerative eye disease, and ocular hypertension, and reduce IOP in subjects in need thereof, comprising administering netarsudil dimesylate and latanoprost to the subject, and thereby induce infringement of the methods of one or more claims of the '901 patent under 35 U.S.C. § 271(b).

286. On information and belief, Micro Labs will sell its Proposed Netarsudil/Latanoprost Product with instructions encouraging or promoting its use by physicians or patients in a manner that will induce the infringement of one or more claims of the '901 patent under 35 U.S.C. § 271(b).

287. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216971, Micro Labs will make, use, offer to sell, or sell Micro Labs' Proposed Netarsudil/Latanoprost Product within the United States, or will import Micro Labs' Proposed Netarsudil/Latanoprost Product into the United States, and will thereby infringe, or induce or contribute to infringement of, one or more claims of the '901 patent.

288. On information and belief, Micro Labs has actual knowledge of the '901 patent, as demonstrated by at least Micro Labs' certification 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) described in Micro Labs' Notice Letter, and was aware that the filing of ANDA No. 216971 would constitute an act of infringement of the '901 patent. Micro Labs has no reasonable basis for asserting that the

commercial manufacture, use, offer for sale, or sale of Micro Labs' Proposed Netarsudil/Latanoprost Product would not infringe one or more claims of the '901 patent.

289. If Micro Labs' infringement of the '901 patent is not permanently enjoined, Aerie will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XVII: INFRINGEMENT OF U.S. PATENT NO. 9,993,470 BY MICRO LABS' ANDA NO. 216971

290. Aerie incorporates each of the preceding paragraphs 1 – 289 as if fully set forth herein.

291. On information and belief, Micro Labs submitted ANDA No. 216971 to the FDA under the provisions of 21 U.S.C. § 355(j).

292. Micro Labs, via its Notice Letter, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil/Latanoprost Product prior to the expiration of the '470 patent.

293. On information and belief, Micro Labs intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil/Latanoprost Product with proposed labeling immediately and imminently upon final approval of its Netarsudil/Latanoprost ANDA.

294. On information and belief, Micro Labs made and included in its Netarsudil/Latanoprost ANDA a Paragraph IV Certification stating that, in Micro Labs' opinion, the '470 patent is invalid, unenforceable and/or not infringed.

295. By submitting and maintaining its Netarsudil/Latanoprost ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sale of its Proposed Netarsudil/Latanoprost Product prior to the expiration of the '470 patent, Micro Labs

has committed an act of infringement of one or more claims of the '470 patent under 35 U.S.C. § 271(e)(2)(A).

296. Micro Labs' Notice Letter states that Micro Labs' Proposed Netarsudil/Latanoprost Product contains (S)-4-(3-amino-1-(isoquinolin-6-yl-amino)-1-oxopropan-2-yl) benzyl 2,4-dimethylbenzoate dimesylate, commonly known as netarsudil dimesylate (a pharmaceutically acceptable salt of netarsudil), and isopropyl-(Z)-7[1R,2R,3R,5S) 3,5-dihydroxy-2-[(3R)-3-hydroxy-5-phenylpentyl]cyclopentyl]-5-heptenoate, commonly known as latanoprost, and that the dosage form is an ophthalmic solution.

297. Thus, on information and belief, Micro Labs' Proposed Netarsudil/Latanoprost Product will directly infringe one or more of the claims of the '470 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

298. On information and belief, Micro Labs' Netarsudil/Latanoprost ANDA seeks FDA approval of Micro Labs' Proposed Netarsudil/Latanoprost Product for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension, and the recommended dosage of Micro Labs' Proposed Netarsudil/Latanoprost Product will be one drop in the affected eye(s) once daily in the evening.

299. On information and belief, Micro Labs' Proposed Netarsudil/Latanoprost Product is especially made or adapted for use in infringing the '470 patent, and Micro Labs' Proposed Netarsudil/Latanoprost Product is not suitable for any substantial noninfringing use.

300. Thus, on information and belief, Micro Labs will contribute to the infringement of one or more claims of the '470 patent under 35 U.S.C. § 271(c).

301. On information and belief, Micro Labs' Proposed Netarsudil/Latanoprost Product, if approved and marketed, will be accompanied by a product label that will induce physicians to

treat ocular disorders, including glaucoma, in subjects in need thereof, comprising administering a composition comprising netarsudil dimesylate and latanoprost topically to an eye of the subject, and thereby induce infringement of the methods of one or more claims of the '470 patent under 35 U.S.C. § 271(b).

302. On information and belief, Micro Labs will sell its Proposed Netarsudil/Latanoprost Product with instructions encouraging or promoting its use by physicians or patients in a manner that will induce the infringement of one or more claims of the '470 patent under 35 U.S.C. § 271(b).

303. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216971, Micro Labs will make, use, offer to sell, or sell Micro Labs' Proposed Netarsudil/Latanoprost Product within the United States, or will import Micro Labs' Proposed Netarsudil/Latanoprost Product into the United States, and will thereby infringe, or induce or contribute to infringement of, one or more claims of the '470 patent.

304. On information and belief, Micro Labs has actual knowledge of the '470 patent, as demonstrated by at least Micro Labs' certification 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) described in Micro Labs' Notice Letter, and was aware that the filing of ANDA No. 216971 would constitute an act of infringement of the '470 patent. Micro Labs has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Micro Labs' Proposed Netarsudil/Latanoprost Product would not infringe one or more claims of the '470 patent.

305. If Micro Labs' infringement of the '470 patent is not permanently enjoined, Aerie will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XVIII: INFRINGEMENT OF
U.S. PATENT NO. 11,197,853 BY MICRO LABS' ANDA NO. 216971

306. Aerie incorporates each of the preceding paragraphs 1 – 305 as if fully set forth herein.

307. On information and belief, Micro Labs submitted ANDA No. 216971 to the FDA under the provisions of 21 U.S.C. § 355(j).

308. Micro Labs, via its Notice Letter, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil/Latanoprost Product prior to the expiration of the '853 patent.

309. On information and belief, Micro Labs intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed Netarsudil/Latanoprost Product with proposed labeling immediately and imminently upon final approval of its Netarsudil/Latanoprost ANDA.

310. On information and belief, Micro Labs made and included in its Netarsudil/Latanoprost ANDA a Paragraph IV Certification stating that, in Micro Labs' opinion, the '853 patent is invalid, unenforceable and/or not infringed.

311. By submitting and maintaining its Netarsudil/Latanoprost ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sale of its Proposed Netarsudil/Latanoprost Product prior to the expiration of the '853 patent, Micro Labs has committed an act of infringement of one or more claims of the '853 patent under 35 U.S.C. § 271(e)(2)(A).

312. Micro Labs' Notice Letter states that Micro Labs' Proposed Netarsudil/Latanoprost Product contains (S)-4-(3-amino-1-(isoquinolin-6-yl-amino)-1-oxopropan-2-yl) benzyl 2,4-dimethylbenzoate dimesylate, commonly known as netarsudil dimesylate (a pharmaceutically

acceptable salt of netarsudil; strength is equivalent to 0.02% of netarsudil base), and isopropyl-(Z)-7[1R,2R,3R,5S) 3,5-dihydroxy-2-[(3R)-3-hydroxy-5-phenylpentyl]cyclopentyl]-5-heptenoate, commonly known as latanoprost (strength is 0.005%), and that the dosage form is an ophthalmic solution.

313. On information and belief, because Micro Labs' Proposed Netarsudil/Latanoprost Product is in the form of an ophthalmic solution, it will be a pharmaceutical composition and will comprise about 0.02% (w/v) (S)-4-(3-amino-1-(isoquinolin-6-yl-amino)-1-oxopropan-2-yl) benzyl 2,4-dimethylbenzoate dimesylate (a dimesylate salt), about 0.005% (w/v) isopropyl-(Z)-7[1R,2R,3R,5S) 3,5-dihydroxy-2-[(3R)-3-hydroxy-5-phenylpentyl]cyclopentyl]-5-heptenoate (a prostaglandin analog), and at least one pharmaceutically acceptable excipient or an equivalent.

314. Thus, on information and belief, Micro Labs' Proposed Netarsudil/Latanoprost Product will directly infringe one or more claims of the '853 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

315. On information and belief, Micro Labs' Proposed Netarsudil/Latanoprost Product is especially made or adapted for use in infringing the '853 patent, and Micro Labs' Proposed Netarsudil/Latanoprost Product is not suitable for any substantial noninfringing use.

316. Thus, on information and belief, Micro Labs will contribute to the infringement of one or more claims of the '853 patent under 35 U.S.C. § 271(c).

317. On information and belief, Micro Labs will sell its Proposed Netarsudil/Latanoprost Product with instructions encouraging or promoting its use by physicians or patients in a manner that will induce the infringement of one or more claims of the '853 patent under 35 U.S.C. § 271(b).

318. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216971, Micro Labs will make, use, offer to sell, or sell Micro Labs' Proposed Netarsudil/Latanoprost Product within the United States, or will import Micro Labs' Proposed Netarsudil/Latanoprost Product into the United States, and will thereby infringe, or induce or contribute to infringement of, one or more claims of the '853 patent.

319. On information and belief, Micro Labs has actual knowledge of the '853 patent, as demonstrated by at least Micro Labs' certification 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) described in Micro Labs' Notice Letter, and was aware that the filing of ANDA No. 216971 would constitute an act of infringement of the '853 patent. Micro Labs has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Micro Labs' Proposed Netarsudil/Latanoprost Product would not infringe one or more claims of the '853 patent.

320. If Micro Labs' infringement of the '853 patent is not permanently enjoined, Aerie will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Aerie respectfully requests the following relief:

A. A judgment that Micro Labs' submission and maintenance of its ANDA No. 216972 constituted an act of infringement of the '826 patent;

B. A judgment that Micro Labs' submission and maintenance of its ANDA No. 216971 constituted an act of infringement of the '826 patent;

C. A judgment declaring that Micro Labs' making, using, offering to sell, or selling in the United States or importing into the United States of its Proposed Netarsudil Product will infringe the '826 patent;

D. A judgment declaring that Micro Labs' making, using, offering to sell, or selling in the United States or importing into the United States of its Proposed Netarsudil/Latanoprost Product will infringe the '826 patent;

E. A permanent injunction restraining and enjoining Micro Labs, its affiliates, subsidiaries, and each of its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of its Proposed Netarsudil Product until the expiration of the '826 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '826 patent is or becomes entitled;

F. A permanent injunction restraining and enjoining Micro Labs, its affiliates, subsidiaries, and each of its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of its Proposed Netarsudil/Latanoprost Product until the expiration of the '826 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '826 patent is or becomes entitled;

G. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Micro Labs' ANDA No. 216972 shall be a date that is not earlier than the expiration date of the '826 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '826 patent is or becomes entitled;

H. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Micro Labs' ANDA No. 216971 shall be a date that is not earlier than the expiration date of the '826 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '826 patent is or becomes entitled;

I. A judgment that Micro Labs' submission and maintenance of its ANDA No. 216972 constituted an act of infringement of the '017 patent;

J. A judgment that Micro Labs' submission and maintenance of its ANDA No. 216971 constituted an act of infringement of the '017 patent;

K. A judgment declaring that Micro Labs' making, using, offering to sell, or selling in the United States or importing into the United States of its Proposed Netarsudil Product will infringe the '017 patent;

L. A judgment declaring that Micro Labs' making, using, offering to sell, or selling in the United States or importing into the United States of its Proposed Netarsudil/Latanoprost Product will infringe the '017 patent;

M. A permanent injunction restraining and enjoining Micro Labs, its affiliates, subsidiaries, and each of its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of its Proposed Netarsudil Product until the expiration of the '017 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '017 patent is or becomes entitled;

N. A permanent injunction restraining and enjoining Micro Labs, its affiliates, subsidiaries, and each of its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of its Proposed Netarsudil/Latanoprost Product until the expiration of the '017 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '017 patent is or becomes entitled;

O. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Micro Labs' ANDA No. 216972 shall be a date that is not earlier than the expiration date of the '017 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '017 patent is or becomes entitled;

P. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Micro Labs' ANDA No. 216971 shall be a date that is not earlier than the expiration date of the '017 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '017 patent is or becomes entitled;

Q. A judgment that Micro Labs' submission and maintenance of its ANDA No. 216972 constituted an act of infringement of the '844 patent;

R. A judgment that Micro Labs' submission and maintenance of its ANDA No. 216971 constituted an act of infringement of the '844 patent;

S. A judgment declaring that Micro Labs' making, using, offering to sell, or selling in the United States or importing into the United States of its Proposed Netarsudil Product will infringe the '844 patent;

T. A judgment declaring that Micro Labs' making, using, offering to sell, or selling in the United States or importing into the United States of its Proposed Netarsudil/Latanoprost Product will infringe the '844 patent;

U. A permanent injunction restraining and enjoining Micro Labs, its affiliates, subsidiaries, and each of its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of its Proposed Netarsudil Product until

the expiration of the ’844 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the ’844 patent is or becomes entitled;

V. A permanent injunction restraining and enjoining Micro Labs, its affiliates, subsidiaries, and each of its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of its Proposed Netarsudil/Latanoprost Product until the expiration of the ’844 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the ’844 patent is or becomes entitled;

W. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Micro Labs’ ANDA No. 216972 shall be a date that is not earlier than the expiration date of the ’844 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the ’844 patent is or becomes entitled;

X. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Micro Labs’ ANDA No. 216971 shall be a date that is not earlier than the expiration date of the ’844 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the ’844 patent is or becomes entitled;

Y. A judgment that Micro Labs’ submission and maintenance of its ANDA No. 216972 constituted an act of infringement of the ’081 patent;

Z. A judgment that Micro Labs’ submission and maintenance of its ANDA No. 216971 constituted an act of infringement of the ’081 patent;

AA. A judgment declaring that Micro Labs’ making, using, offering to sell, or selling in the United States or importing into the United States of its Proposed Netarsudil Product will infringe the ’081 patent;

BB. A judgment declaring that Micro Labs' making, using, offering to sell, or selling in the United States or importing into the United States of its Proposed Netarsudil/Latanoprost Product will infringe the '081 patent;

CC. A permanent injunction restraining and enjoining Micro Labs, its affiliates, subsidiaries, and each of its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of its Proposed Netarsudil Product until the expiration of the '081 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '081 patent is or becomes entitled;

DD. A permanent injunction restraining and enjoining Micro Labs, its affiliates, subsidiaries, and each of its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of its Proposed Netarsudil/Latanoprost Product until the expiration of the '081 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '081 patent is or becomes entitled;

EE. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Micro Labs' ANDA No. 216972 shall be a date that is not earlier than the expiration date of the '081 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '081 patent is or becomes entitled;

FF. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Micro Labs' ANDA No. 216971 shall be a date that is not earlier than the expiration date of the '081 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '081 patent is or becomes entitled;

GG. A judgment that Micro Labs' submission and maintenance of its ANDA No. 216972 constituted an act of infringement of the '043 patent;

HH. A judgment that Micro Labs' submission and maintenance of its ANDA No. 216971 constituted an act of infringement of the '043 patent;

II. A judgment declaring that Micro Labs' making, using, offering to sell, or selling in the United States or importing into the United States of its Proposed Netarsudil Product will infringe the '043 patent;

JJ. A judgment declaring that Micro Labs' making, using, offering to sell, or selling in the United States or importing into the United States of its Proposed Netarsudil/Latanoprost Product will infringe the '043 patent;

KK. A permanent injunction restraining and enjoining Micro Labs, its affiliates, subsidiaries, and each of its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of its Proposed Netarsudil Product until the expiration of the '043 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '043 patent is or becomes entitled;

LL. A permanent injunction restraining and enjoining Micro Labs, its affiliates, subsidiaries, and each of its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of its Proposed Netarsudil/Latanoprost Product until the expiration of the '043 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '043 patent is or becomes entitled;

MM. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Micro Labs' ANDA No. 216972 shall be a date that is not earlier than the expiration date of the '043 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '043 patent is or becomes entitled;

NN. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Micro Labs' ANDA No. 216971 shall be a date that is not earlier than the expiration date of the '043 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '043 patent is or becomes entitled;

OO. A judgment that Micro Labs' submission and maintenance of its ANDA No. 216972 constituted an act of infringement of the '336 patent;

PP. A judgment that Micro Labs' submission and maintenance of its ANDA No. 216971 constituted an act of infringement of the '336 patent;

QQ. A judgment declaring that Micro Labs' making, using, offering to sell, or selling in the United States or importing into the United States of its Proposed Netarsudil Product will infringe the '336 patent;

RR. A judgment declaring that Micro Labs' making, using, offering to sell, or selling in the United States or importing into the United States of its Proposed Netarsudil/Latanoprost Product will infringe the '336 patent;

SS. A permanent injunction restraining and enjoining Micro Labs, its affiliates, subsidiaries, and each of its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of its Proposed Netarsudil Product until

the expiration of the ’336 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the ’336 patent is or becomes entitled;

TT. A permanent injunction restraining and enjoining Micro Labs, its affiliates, subsidiaries, and each of its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of its Proposed Netarsudil/Latanoprost Product until the expiration of the ’336 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the ’336 patent is or becomes entitled;

UU. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Micro Labs’ ANDA No. 216972 shall be a date that is not earlier than the expiration date of the ’336 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the ’336 patent is or becomes entitled;

VV. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Micro Labs’ ANDA No. 216971 shall be a date that is not earlier than the expiration date of the ’336 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the ’336 patent is or becomes entitled;

WW. A judgment that Micro Labs’ submission and maintenance of its ANDA No. 216972 constituted an act of infringement of the ’538 patent;

XX. A judgment that Micro Labs’ submission and maintenance of its ANDA No. 216971 constituted an act of infringement of the ’538 patent;

YY. A judgment declaring that Micro Labs’ making, using, offering to sell, or selling in the United States or importing into the United States of its Proposed Netarsudil Product will infringe the ’538 patent;

ZZ. A judgment declaring that Micro Labs' making, using, offering to sell, or selling in the United States or importing into the United States of its Proposed Netarsudil/Latanoprost Product will infringe the '538 patent;

AAA. A permanent injunction restraining and enjoining Micro Labs, its affiliates, subsidiaries, and each of its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of its Proposed Netarsudil Product until the expiration of the '538 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '538 patent is or becomes entitled;

BBB. A permanent injunction restraining and enjoining Micro Labs, its affiliates, subsidiaries, and each of its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of its Proposed Netarsudil/Latanoprost Product until the expiration of the '538 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '538 patent is or becomes entitled;

CCC. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Micro Labs' ANDA No. 216972 shall be a date that is not earlier than the expiration date of the '538 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '538 patent is or becomes entitled;

DDD. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Micro Labs' ANDA No. 216971 shall be a date that is not earlier than the expiration date of the '538 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '538 patent is or becomes entitled;

EEE. A judgment that Micro Labs' submission and maintenance of its ANDA No. 216972 constituted an act of infringement of the '901 patent;

FFF. A judgment that Micro Labs' submission and maintenance of its ANDA No. 216971 constituted an act of infringement of the '901 patent;

GGG. A judgment declaring that Micro Labs' making, using, offering to sell, or selling in the United States or importing into the United States of its Proposed Netarsudil Product will infringe the '901 patent;

HHH. A judgment declaring that Micro Labs' making, using, offering to sell, or selling in the United States or importing into the United States of its Proposed Netarsudil/Latanoprost Product will infringe the '901 patent;

III. A permanent injunction restraining and enjoining Micro Labs, its affiliates, subsidiaries, and each of its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of its Proposed Netarsudil Product until the expiration of the '901 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '901 patent is or becomes entitled;

JJJ. A permanent injunction restraining and enjoining Micro Labs, its affiliates, subsidiaries, and each of its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of its Proposed Netarsudil/Latanoprost Product until the expiration of the '901 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '901 patent is or becomes entitled;

KKK. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Micro Labs' ANDA No. 216972 shall be a date that is not earlier than the expiration date of the '901 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '901 patent is or becomes entitled;

LLL. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Micro Labs' ANDA No. 216971 shall be a date that is not earlier than the expiration date of the '901 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '901 patent is or becomes entitled;

MMM. A judgment that Micro Labs' submission and maintenance of its ANDA No. 216971 constituted an act of infringement of the '470 patent;

NNN. A judgment declaring that Micro Labs' making, using, offering to sell, or selling in the United States or importing into the United States of its Proposed Netarsudil/Latanoprost Product will infringe the '470 patent;

OOO. A permanent injunction restraining and enjoining Micro Labs, its affiliates, subsidiaries, and each of its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of its Proposed Netarsudil/Latanoprost Product until the expiration of the '470 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '470 patent is or becomes entitled;

PPP. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Micro Labs' ANDA No. 216971 shall be a date that is not earlier than the expiration date of the '470 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '470 patent is or becomes entitled;

QQQ. A judgment that Micro Labs' submission and maintenance of its ANDA No. 216971 constituted an act of infringement of the '853 patent;

RRR. A judgment declaring that Micro Labs' making, using, offering to sell, or selling in the United States or importing into the United States of its Proposed Netarsudil/Latanoprost Product will infringe the '853 patent;

SSS. A permanent injunction restraining and enjoining Micro Labs, its affiliates, subsidiaries, and each of its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of its Proposed Netarsudil/Latanoprost Product until the expiration of the '853 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '853 patent is or becomes entitled;

TTT. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Micro Labs' ANDA No. 216971 shall be a date that is not earlier than the expiration date of the '853 patent, including any extensions and/or periods of exclusivity to which Aerie and/or the '853 patent is or becomes entitled;

UUU. Damages, including monetary and other relief, to Aerie if Micro Labs engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of its Proposed Netarsudil Product prior to the expiration date of 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, including any extensions and/or additional periods of exclusivity to which Aerie is or becomes entitled;

VVV. Damages, including monetary and other relief, to Aerie if Micro Labs engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of its

Proposed Netarsudil/Latanoprost Product prior to the expiration date 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, the '470 patent, and the '853 patent, including any extensions and/or additional periods of exclusivity to which Aerie is or becomes entitled;

WWW. A declaration that this case is "exceptional" within the meaning of 35 U.S.C. § 285 and an award of reasonable attorney fees, costs, expenses, and disbursements of this action; and

XXX. Such other and further relief as the Court may deem just and proper.

March 14, 2022

s/Liza M. Walsh

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Local Rule 11.2 Certification

We hereby certify that the matter in controversy is not the subject of any action pending in any court or of any arbitration or administrative proceeding, but is related to the following action:

- *Aerie Pharmaceuticals, Inc., et al. v. Gland Pharma Limited*, No. 3:22-1359 (D.N.J.); and
- *Aerie Pharmaceuticals, Inc., et al. v. Orbicular Pharmaceutical Technologies*, No. 3:22-1364 (D.N.J.).

March 14, 2022

s/Liza M. Walsh

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Local Rule 201.1 Certification

We hereby certify that the above captioned matter is not subject to compulsory arbitration in that Plaintiffs seek, *inter alia*, injunctive relief.

March 14, 2022

s/Liza M. Walsh

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