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

AERIE PHARMACEUTICALS, INC. and AERIE DISTRIBUTION, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
GLAND PHARMA LIMITED,	)	
Defendant.	)	

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 Gland Pharma Limited ("Gland") to the U.S. Food and Drug Administration ("FDA") for approval to engage in the commercial manufacture, use, or sale of netarsudil dimesylate ophthalmic solution, 0.02%, for topical ophthalmic use, a generic version of Aerie's RHOPRESSA® prior to the expiration of U.S. Patent Nos. 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").

THE PARTIES

2. 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.

3. 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.

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

5. On information and belief, Defendant Gland is a company organized and existing under the laws of the Republic of India, having a place of business at Survey No. 143-148, 150 & 151, Near Gandimaisamma 'X' Roads, D.P. Pally, Dundigal Gandimaisamma Mandal, Medchal-Malkjgiri District, Hyderabad, Telangana, 500043 India. On information and belief, Gland 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.

6. On information and belief, Gland assembled and caused to be submitted to the FDA ANDA No. 216855 pursuant to 21 U.S.C. § 355(j) (§ 505(j) of the FDCA) (hereinafter "Gland's ANDA") concerning a proposed drug product, netarsudil ophthalmic solution, 0.02%, for topical ophthalmic use (hereinafter "Gland's Proposed ANDA Product"). Gland's ANDA refers to and relies upon Aerie's NDA No. 208254 for RHOPRESSA®.

7. By letter dated January 31, 2022 ("Gland's Notice Letter"), Gland notified Aerie Pharmaceuticals, Inc. that, as a part of its ANDA, Gland 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 '043 patent, the '336 patent, the '901 patent, and the '538 patent, each of which is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for RHOPRESSA®, asserting that the '043 patent, the '336 patent, the '901 patent, and the '538 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Gland's Proposed ANDA Product.

JURISDICTION AND VENUE

8. 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).

9. This Court has personal jurisdiction over Gland because, *inter alia*, Gland 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, Gland 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.

10. In addition, this Court has personal jurisdiction over Gland because, among other things, on information and belief, (1) Gland filed Gland's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, sale, or offer for sale of Gland's Proposed ANDA Product in the United States, including in New Jersey, and (2) upon approval of Gland's ANDA, Gland will market, distribute, offer for sale, sell, and/or import Gland's Proposed ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Gland's Proposed ANDA Product in New Jersey. On information and

belief, upon approval of Gland's ANDA, Gland's Proposed ANDA Product 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.

11. In addition, this Court has personal jurisdiction over Gland because it regularly engages in patent litigation concerning Gland's 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.*, *Fresenius Kabi USA, LLC et al. v. Gland Pharma Ltd.*, C.A. No. 20-cv-12347-FLW-TJB, D.I. 6 (D.N.J. Jan. 15, 2021); *Merck Sharpe & Dohme BV et al. v. Gland Pharma Ltd.*, C.A. No. 20-cv-02750-CCC-MF, D.I. 8 (D.N.J. Apr. 3, 2020); *Chiesi USA, Inc. et al. v. Gland Pharma Ltd.*, C.A. No. 19-cv-21204-MCA-MAH, D.I. 7 (D.N.J. Dec. 16, 2019); *Medicure Int'l, Inc. v. Gland Pharma Ltd.*, C.A. No. 18-cv-16246-KM-MAH, D.I. 13 (D.N.J. Jan. 23, 2019).

12. In the alternative, Gland 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).

13. 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 Gland to litigate this action in this District, and Gland is subject to personal jurisdiction in this District.

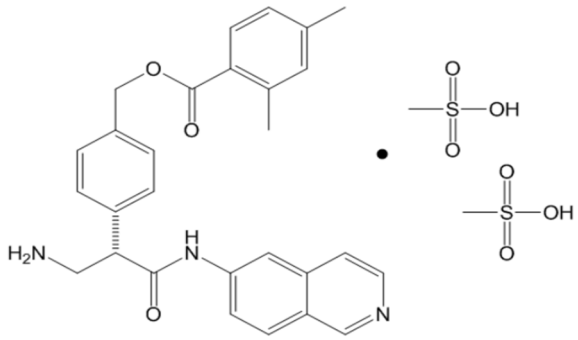
14. Venue is proper in this district for Gland under 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Gland is a corporation existing under the laws of India and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

RHOPRESSA®

15. 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.

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

17. 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:



18. 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).

THE PATENTS-IN-SUIT

19. United States Patent No. 9,415,043 (copy attached as Exhibit A) 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 RHOPRESSA®.

20. United States Patent No. 9,931,336 (copy attached as Exhibit B) 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 use of RHOPRESSA® in accordance with the labeling approved by the FDA. It is listed in the Orange Book for RHOPRESSA®.

21. United States Patent No. 11,185,538 (copy attached as Exhibit C) 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 RHOPRESSA®.

22. United States Patent No. 10,588,901 (copy attached as Exhibit D) 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 relies on the same provisional patent application as the '043, '336, and '538 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 use of RHOPRESSA® in accordance with the labeling approved by the FDA. It is listed in the Orange Book for RHOPRESSA®.

23. The submission of Gland's ANDA and Gland's intention to commercially manufacture, use, offer for sale, sell, and/or import Gland's Proposed ANDA Product upon receiving FDA approval create an actual case or controversy with respect to infringement of the '043 patent, the '336 patent, the '538 patent, and the '901 patent.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 9,415,043

24. Aerie incorporates each of the preceding paragraphs 1 – 23 as if fully set forth herein.

25. On information and belief, Gland submitted ANDA No. 216855 to the FDA under the provisions of 21 U.S.C. § 355(j).

26. Gland, 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 ANDA Product prior to the expiration of the '043 patent.

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

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

29. By submitting and maintaining its ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, or sale of its Proposed ANDA Product prior to the expiration of the '043 patent, Gland 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).

30. Gland's Notice Letter states that Gland's Proposed ANDA 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.

31. Thus, on information and belief, Gland's Proposed ANDA 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.

32. On information and belief, Gland's Proposed ANDA Product is especially made or adapted for use in infringing the '043 patent, and Gland's Proposed ANDA Product is not suitable for any substantial noninfringing use.

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

34. On information and belief, Gland will sell its Proposed ANDA 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).

35. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216855, Gland will make, use, offer to sell, or sell Gland's Proposed ANDA Product within the United States, or will import Gland's Proposed ANDA 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.

36. On information and belief, Gland has actual knowledge of the '043 patent, as demonstrated by at least Gland's 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 Gland's Notice Letter, and was aware that the filing of ANDA No. 216855 would constitute an act of infringement of the '043 patent. Gland has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Gland's Proposed ANDA Product would not infringe claim 1, the sole claim, of the '043 patent.

37. If Gland's 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 II: INFRINGEMENT OF U.S. PATENT NO. 9,931,336

38. Aerie incorporates each of the preceding paragraphs 1 – 37 as if fully set forth herein.

39. On information and belief, Gland submitted ANDA No. 216855 to the FDA under the provisions of 21 U.S.C. § 355(j).

40. Gland, 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 ANDA Product prior to the expiration of the '336 patent.

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

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

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

44. Gland's Notice Letter states that Gland's Proposed ANDA 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.

45. Thus, on information and belief, Gland's Proposed ANDA 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.

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

47. On information and belief, Gland's Proposed ANDA Product is especially made or adapted for use in infringing the '336 patent, and Gland's Proposed ANDA Product is not suitable for any substantial noninfringing use.

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

49. On information and belief, Gland's Proposed ANDA 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).

50. On information and belief, Gland will sell its Proposed ANDA 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).

51. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216855, Gland will make, use, offer to sell, or sell Gland's Proposed ANDA Product within the United States, or will import Gland's Proposed ANDA Product into the United States, and will thereby infringe, or induce or contribute to infringement of, one or more claims of the '336 patent.

52. On information and belief, Gland has actual knowledge of the '336 patent, as demonstrated by at least Gland's 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 Gland's Notice Letter, and was aware that the filing of ANDA No. 216855 would constitute an act of infringement of the '336 patent. Gland has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Gland's Proposed ANDA Product would not infringe one or more claims of the '336 patent.

53. If Gland's 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 III: INFRINGEMENT OF U.S. PATENT NO. 11,185,538

54. Aerie incorporates each of the preceding paragraphs 1 – 53 as if fully set forth herein.

55. On information and belief, Gland submitted ANDA No. 216855 to the FDA under the provisions of 21 U.S.C. § 355(j).

56. Gland, 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 ANDA Product prior to the expiration of the '538 patent.

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

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

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

60. Gland's Notice Letter states that Gland's Proposed ANDA 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.

61. On information and belief, because Gland's Proposed ANDA 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.

62. Thus, on information and belief, Gland's Proposed ANDA 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.

63. On information and belief, Gland's Proposed ANDA Product is especially made or adapted for use in infringing the '538 patent, and Gland's Proposed ANDA Product is not suitable for any substantial noninfringing use.

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

65. On information and belief, Gland will sell its Proposed ANDA 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).

66. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216855, Gland will make, use, offer to sell, or sell Gland's Proposed ANDA Product within the United States, or will import Gland's Proposed ANDA Product into the United States, and will thereby infringe, or induce or contribute to infringement of, one or more claims of the '538 patent.

67. On information and belief, Gland has actual knowledge of the '538 patent, as demonstrated by at least Gland's 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 Gland's Notice Letter, and was aware that the filing of ANDA No. 216855 would constitute an act of infringement of the '538 patent. Gland has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Gland's Proposed ANDA Product would not infringe one or more claims of the '538 patent.

68. If Gland's 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 IV: INFRINGEMENT OF U.S. PATENT NO. 10,588,901

69. Aerie incorporates each of the preceding paragraphs 1 – 68 as if fully set forth herein.

70. On information and belief, Gland submitted ANDA No. 216855 to the FDA under the provisions of 21 U.S.C. § 355(j).

71. Gland, 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 ANDA Product prior to the expiration of the '901 patent.

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

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

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

75. Gland's Notice Letter states that Glands Proposed ANDA 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.

76. Thus, on information and belief, Gland's Proposed ANDA 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.

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

78. On information and belief, Gland's Proposed ANDA Product is especially made or adapted for use in infringing the '901 patent, and Gland's Proposed ANDA Product is not suitable for any substantial noninfringing use.

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

80. On information and belief, Gland's Proposed ANDA 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).

81. On information and belief, Gland will sell its Proposed ANDA 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).

82. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 216855, Gland will make, use, offer to sell, or sell Gland's Proposed ANDA Product within the United States, or will import Gland's Proposed ANDA Product into the United States, and will thereby infringe, or induce or contribute to infringement of, one or more claims of the '901 patent.

83. On information and belief, Gland has actual knowledge of the '901 patent, as demonstrated by at least Gland's 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 Gland's Notice Letter, and was aware that the filing of ANDA No. 216855 would constitute an act of infringement of the '901 patent. Gland has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Gland's Proposed ANDA Product would not infringe one or more claims of the '901 patent.

84. If Gland's infringement of the '901 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 Gland's submission and maintenance of its ANDA No. 216855 constituted an act of infringement of the '043 patent;

B. A judgment declaring that Gland's making, using, offering to sell, or selling in the United States or importing into the United States of its Proposed ANDA Product will infringe the '043 patent;

C. A permanent injunction restraining and enjoining Gland, 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 ANDA 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;

D. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Gland’s ANDA No. 216855 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;

E. A judgment that Gland’s submission and maintenance of its ANDA No. 216855 constituted an act of infringement of the ’336 patent;

F. A judgment declaring that Gland’s making, using, offering to sell, or selling in the United States or importing into the United States of its Proposed ANDA Product will infringe the ’336 patent;

G. A permanent injunction restraining and enjoining Gland, 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 ANDA 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;

H. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Gland’s ANDA No. 216855 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;

I. A judgment that Gland's submission and maintenance of its ANDA No. 216855 constituted an act of infringement of the '538 patent;

J. A judgment declaring that Gland's making, using, offering to sell, or selling in the United States or importing into the United States of its Proposed ANDA Product will infringe the '538 patent;

K. A permanent injunction restraining and enjoining Gland, 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 ANDA 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;

L. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Gland's ANDA No. 216855 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;

M. A judgment that Gland's submission and maintenance of its ANDA No. 216855 constituted an act of infringement of the '901 patent;

N. A judgment declaring that Gland's making, using, offering to sell, or selling in the United States or importing into the United States of its Proposed ANDA Product will infringe the '901 patent;

O. A permanent injunction restraining and enjoining Gland, 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 ANDA 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;

P. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Gland's ANDA No. 216855 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;

Q. Damages, including monetary and other relief, to Aerie if Gland engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of its Proposed ANDA Product prior to the expiration date of 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;

R. 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

S. 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.

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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