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America, Inc.*

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

TARO PHARMACEUTICALS U.S.A., INC.
and TARO PHARMACEUTICALS NORTH
AMERICA, INC.

Plaintiffs,

C.A. No._____

v.

GLENMARK PHARMACEUTICALS LTD.
and GLENMARK PHARMACEUTICALS
INC., USA

Defendants.

**PLAINTIFFS TARO PHARMACEUTICALS U.S.A., INC.
AND TARO PHARMACEUTICALS NORTH AMERICA, INC.'S
COMPLAINT AGAINST GLENMARK PHARMACEUTICALS LTD.
AND GLENMARK PHARMACEUTICALS INC., USA**

Plaintiffs Taro Pharmaceuticals U.S.A., Inc. (“Taro USA”) and Taro Pharmaceuticals North America, Inc. (“Taro North Am.”) (together, “Taro” or “Plaintiffs”) for its complaint against defendants Glenmark Pharmaceuticals Limited (“Glenmark Ltd.”) and Glenmark Pharmaceuticals Inc., USA (“Glenmark USA”) (collectively, “Glenmark” or “Defendants”), to the best of its knowledge, information and belief, allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent Nos. 8,277,780 (the “’780 patent”) (attached as **Exhibit A**) and 8,715,624 (the “’624 patent,”) (attached as **Exhibit B**) under 35 U.S.C. § 271(e)(2) and for Declaratory Judgment of infringement under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a), (b), and (c) relating to Taro’s commercially successful product, Topicort® (desoximetasone) Topical Spray, 0.25%. This action arises from Defendants’ filing of an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug Administration (“FDA”) seeking approval to market a generic version of Topicort® (desoximetasone) Topical Spray, 0.25%, prior to the expiration of the ’780 and ’624 patents.

THE PARTIES

2. Taro USA is a company organized and existing under the laws of the State of New York, with a principal place of business at 3 Skyline Drive, Hawthorne, New York 10532.

3. Taro North Am. is a company organized and existing under the laws of the Cayman Islands, with a principal place of business at 190 Elgin Avenue, George Town, Grand Cayman, KY1-9005, Cayman Islands.

4. On information and belief, Defendant Glenmark Ltd. is a corporation operating and existing under the laws of India, having a principal place of business at Glenmark House, HDO–Corporate Building, Wing A, BD Sawant Marg, Chakala, Off Western Express Highway,

Mumbai 400099, Maharashtra, India. Upon information and belief, Glenmark Ltd. manufactures, distributes, and/or imports generic drugs for sale and use throughout the United States, including in this district.

5. On information and belief, Defendant Glenmark USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 750 Corporate Drive, Mahwah, NJ 07430.

6. On information and belief, Glenmark USA is a wholly-owned subsidiary of Glenmark Ltd.

7. On information and belief, Glenmark USA manufactures, sells, markets, and distributes generic pharmaceutical products throughout the United States, including in this district, in conjunction with or under the direction of Glenmark Ltd. On information and belief, Glenmark Ltd. has previously designated Glenmark USA as its U.S. agent for other ANDA submissions.

8. On information and belief, Glenmark developed its generic Desoximetasone Topical Spray, 0.25% and prepared ANDA No. 211760 for submission. On information and belief, upon receiving approval of its ANDA No. 211760, Glenmark will manufacture, sell, offer to sell, and/or import Glenmark's generic Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml in the United States, including in this district.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, et seq., and the Declaratory Judgment Act. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

10. Based on the facts alleged herein, this Court has personal jurisdiction over both Glenmark Ltd. and Glenmark USA.

11. Glenmark Ltd. has committed an act of patent infringement under 35 U.S.C. §271(e)(2) and intends to manufacture, use, sell, and offer for sale its proposed generic Desoximetasone Topical Spray, 0.25%, in New Jersey. On information and belief, Glenmark Ltd. directed its agent Glenmark USA to participate and collaborate in the research and development of the proposed generic Desoximetasone Topical Spray, 0.25%, and in the preparation and filing of ANDA No. 211760.

12. On information and belief, Glenmark USA, as an agent of Glenmark Ltd., will manufacture, use, sell, and offer for sale the proposed generic Desoximetasone Topical Spray, 0.25%, in New Jersey.

13. This Court has personal jurisdiction over Glenmark Ltd. and Glenmark USA. Glenmark USA avails itself of the benefits and protections of the laws of the State of New Jersey. For example, Glenmark USA is registered to do business in the State of New Jersey under Business ID Number 0400025135, and Glenmark USA is registered with the State of New Jersey as a manufacturer and wholesale distributor of drugs under Registration Number 5003119.

14. This Court also has personal jurisdiction over Glenmark Ltd. and Glenmark USA by virtue of their systematic and continuous contacts with the State of New Jersey. On information and belief, Glenmark Ltd., Glenmark USA, and their affiliates maintain a U.S. Headquarters in Mahwah, NJ, and maintain U.S. Offices at 461 From Road, Paramus, NJ, 07652. Glenmark Ltd. and Glenmark USA sell, offer for sale, and distribute generic pharmaceuticals throughout the State of New Jersey.

15. On information and belief, Glenmark has at all relevant times maintained continuous and systematic contacts with the State of New Jersey, including but not limited to, its

aforementioned business of preparing generic pharmaceuticals that Glenmark distributes throughout the United States.

16. If ANDA No. 211760 is approved, Glenmark's proposed generic Desoximetasone Topical Spray, 0.25%, would be marketed and distributed in New Jersey by Glenmark USA and/or Glenmark Ltd., and/or prescribed by physicians practicing in this state, and dispensed by pharmacies located in this state, all of which would have a substantial effect on commerce.

17. Glenmark has previously availed themselves of the jurisdiction of this Court by filing suit in this district, consenting to jurisdiction in this district, and/or asserting counterclaims in at least the following civil actions initiated in this district: *Sanofi-Aventis U.S. LLC et al. v. Glenmark Pharmaceuticals Inc., USA, et al.*, No. 3:15-cv-02523(MAS)(LHG), (D.N.J. 2015); *Symed Labs Ltd. et al. v. Glenmark Pharmaceuticals Inc., USA*, No. 2:15-cv-08306-MCA-MAH, (D.N.J. 2015); *Teva Pharmaceutical Industries Ltd. et al. v. Glenmark Generics Inc., USA, et al.*, No. 08-cv-4355(GEB)(JJH), (D.N.J. 2008); *Glenmark Generics, Inc., USA v. Levista, Inc.*, No. 09-1300(FHS), (D.N.J. 2009); *Schering Corp. et al. v. Glenmark Pharmaceuticals, Inc., USA, et al.*, No. 07-cv-001334(JLL), (D.N.J. 2007); *Sanofi-Aventis Deutschland GmbH et al. v. Glenmark Pharmaceuticals Inc., USA, et al.*, No. 07-cv-05855(DMC-MF), (D.N.J. 2007).

18. Venue is proper in this district under 28 U.S.C. § 1400(b).

19. Venue is proper in this district under 28 U.S.C. § 1400(b) because Glenmark "committed an act of infringement" in this district and has a "regular place and established place of business" in this district. Glenmark submitted ANDA No. 211760 pursuant to 505(j)(2)(B)(ii) of the FDCA, and, upon receiving approval of the ANDA, will manufacture, sell, offer to sell, and/or import its proposed generic Desoximetasone Topical Spray, 0.25%, throughout the United States, including in this district. Thus, Glenmark has committed an act of infringement in this

district. Glenmark Ltd. and/or Glenmark USA also have a “regular and established place of business” at its U.S. Headquarters in Mahwah, NJ, and at its U.S. Offices in Paramus, NJ.

BACKGROUND

The FDA Marketing Approval Process

20. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the FDA follows when considering the approval of applications for both brand-name and generic drugs.

21. Under the Hatch-Waxman Amendments, an applicant seeking to market a new brand-name drug must prepare a New Drug Application (“NDA”) for consideration by the FDA. *See* 21 U.S.C. § 355.

22. An NDA must include, among other things, the patent number of any patent that claims the drug or a method of using such drug, for which the applicant submitted the NDA and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1) and (c)(2); 21 C.F.R. §§ 314.53(b) and (c)(2).

23. Upon approval of the NDA, the FDA publishes patent information for the approved drug in its publication, Approved Drug Products with Therapeutic Equivalence Evaluation (“Orange Book”). *See* 21 U.S.C. § 355(j)(7)(A)(iii).

24. A pharmaceutical company may seek to market a generic version of the innovator’s brand drug by submitting an Abbreviated New Drug Application (“ANDA”) under 21 U.S.C. § 355(j). The generic company may then rely on the studies the innovator includes in its NDA.

Taro's Topicort® Product

25. On April 11, 2013, the FDA approved Taro's NDA for Topicort® (desoximetasone) Topical Spray, NDA No. 204141. Taro began marketing Topicort® shortly after that approval.

26. Topicort® is a corticosteroid indicated for the treatment of plaque psoriasis in patients 18 years of age or older. Psoriasis is a systemic inflammatory disease of immune dysfunction that affects an estimated 2%-3% of the U.S. population.

Taro's Patents Covering Topicort®

27. The United States Patent & Trademark Office ("PTO") legally issued the '780 patent, titled "Stable Liquid Desoximetasone Compositions with Reduced Oxidized Impurity" on October 2, 2012. Taro North Am. owns the '780 patent, which lists Srinivasa Rao, Suresh Dixit, Avraham Yacobi, and Arthur Bailey as its inventors. The invention provides a liquid formulation that contains ranges of desoximetasone, isopropyl myristate, a C₂-C₄ alcohol, and a stabilizing agent. The invention also provides processes for preparing such liquid formulations and methods for treating corticosteroid responsive dermatosis, including plaque psoriasis with such liquid formulations.

28. The PTO legally issued the '624 patent, titled "Stable Liquid Desoximetasone Compositions with Reduced Oxidized Impurity" on May 6, 2014. Taro North Am. owns the '624 patent, which lists Srinivasa Rao, Suresh Dixit, Avraham Yacobi, and Arthur Bailey as its inventors. The invention provides a liquid formulation that contains ranges of desoximetasone, isopropyl myristate, a C₂-C₄ alcohol, and a stabilizing agent. The invention also provides processes for preparing such liquid formulations and methods for treating corticosteroid responsive dermatosis, including plaque psoriasis, with such liquid formulations.

29. In conjunction with NDA No. 204141, Taro has listed the '780 and '624 patents with the FDA. The FDA has published the '780 and '624 patents in the Orange Book for NDA No. 204141 covering Topicort® (Desoximetasone) Topical Spray, 0.25%.

Glenmark's ANDA

30. Glenmark submitted ANDA No. 211760 under § 505(j) of the FFDCA (21 U.S.C. § 355(j)) seeking FDA approval to commercially manufacture, use, offer for sale, or sell a generic version of Topicort® (desoximetasone) Topical Spray, 0.25%, throughout the United States prior to the expiration of the '780 and '624 patents.

31. Pursuant to § 505(j)(2)(A)(vii)(IV) of the FFDCA, Glenmark submitted a Paragraph IV Certification in ANDA No. 211760 that alleged that the claims of the '780 and '624 patents are invalid, unenforceable, and/or will not be infringed by its manufacture, use, or sale of its proposed generic Desoximetasone Topical Spray, 0.25%.

32. Taro received written notification of ANDA No. 211760 and Glenmark's allegations under § 505(j)(2)(A)(vii)(IV) on or about June 26, 2018 ("Paragraph IV Notice").

33. The Paragraph IV Notice stated that Glenmark had filed a Paragraph IV Certification with the FDA in conjunction with ANDA No. 211760 which alleged that the claims of the '780 and '624 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale throughout the United States of the proposed generic Desoximetasone Topical Spray, 0.25%.

34. Glenmark has made, and continues to make, substantial preparation to manufacture, offer to sell, sell and/or import its proposed generic Desoximetasone Topical Spray, 0.25%, in the United States prior to expiration of the '780 and '624 patents.

35. Glenmark's actions, including, but not limited to, the development of Glenmark's proposed generic Desoximetasone Topical Spray, 0.25%, and the filing of ANDA No. 211760

with a Paragraph IV Certification, indicate a continued course of conduct to seek FDA approval of ANDA No. 211760 and to manufacture, market, and sell the product after such approval.

COUNT I

(Infringement of the '780 Patent Under 35 U.S.C. § 271(e)(2)(A) by Glenmark's Proposed Generic Desoximetasone Topical Spray, 0.25%)

36. Taro incorporates each of the preceding paragraphs as if fully set forth herein.
37. Glenmark submitted ANDA No. 211760 to FDA under section 505(j) of the FDCA to obtain approval to engage in the manufacture, use or sale throughout the United States, of Glenmark's proposed generic Desoximetasone Topical Spray, 0.25%, prior to the expiration of the '780 patent. By submitting ANDA No. 211760, Glenmark has committed an act of infringement of the '780 patent under 35 U.S.C. § 271(e)(2)(A).
38. The commercial manufacture, use, offer for sale, sale, and/or importation of Glenmark's proposed generic Desoximetasone Topical Spray, 0.25%, prior to the expiration of the '780 patent will constitute an act of infringement of the '780 patent.
39. On information and belief, Glenmark became aware of the '780 patent no later than the date on which that patent was listed in the Orange Book.
40. On information and belief, Glenmark knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of their proposed generic Desoximetasone Topical Spray, 0.25%, will actively induce and contribute to the actual infringement of the '780 patent.
41. On information and belief, Glenmark knows or should know that Glenmark's proposed generic Desoximetasone Topical Spray, 0.25%, will be especially made for or especially adapted for use in infringement of the '780 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial

manufacture, use, offer for sale, sale, and/or importation of its proposed generic Desoximetasone Topical Spray, 0.25%, will actively contribute to the actual infringement of the '780 patent.

42. The commercial manufacture, use, offer for sale, sale and/or importation of Glenmark's generic Desoximetasone Topical Spray, 0.25%, in violation of Taro's patent rights will cause harm to Taro for which damages are inadequate.

43. Taro does not have an adequate remedy at law and will be irreparably harmed by Glenmark's infringing conduct unless such conduct is enjoined by this Court.

COUNT II

(Infringement of the '624 Patent Under 35 U.S.C. § 271(e)(2)(A) by Glenmark's Proposed Generic Desoximetasone Topical Spray, 0.25%)

44. Taro incorporates each of the preceding paragraphs as if fully set forth herein.

45. Glenmark submitted ANDA No. 211760 to FDA under section 505(j) of the FDCA to obtain approval to engage in the manufacture, use or sale throughout the United States, of Glenmark's proposed generic Desoximetasone Topical Spray, 0.25%, prior to the expiration of the '624 patent. By submitting ANDA No. 211760, Glenmark has committed an act of infringement of the '624 patent under 35 U.S.C. § 271(e)(2)(A).

46. The commercial manufacture, use, offer for sale, sale, and/or importation of Glenmark's proposed generic Desoximetasone Topical Spray, 0.25%, prior to the expiration of the '624 patent will constitute an act of infringement of the '624 patent.

47. On information and belief, Glenmark became aware of the '624 patent no later than the date on which that patent was listed in the Orange Book.

48. On information and belief, Glenmark knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of their proposed generic

Desoximetasone Topical Spray, 0.25%, will actively induce and contribute to the actual infringement of the '624 patent.

49. On information and belief, Glenmark knows or should know that Glenmark's proposed generic Desoximetasone Topical Spray, 0.25%, will be especially made for or especially adapted for use in infringement of the '624 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Desoximetasone Topical Spray, 0.25%, will actively contribute to the actual infringement of the '624 patent.

50. The commercial manufacture, use, offer for sale, sale and/or importation of Glenmark's generic Desoximetasone Topical Spray, 0.25%, in violation of Taro's patent rights will cause harm to Taro for which damages are inadequate.

51. Taro does not have an adequate remedy at law and will be irreparably harmed by Glenmark's infringing conduct unless such conduct is enjoined by this Court.

COUNT III

(Declaratory Judgment of Infringement of the '780 Patent Under U.S.C. § 271(a) by Glenmark's Proposed Generic Desoximetasone Topical Spray, 0.25%)

52. Taro incorporates each of the preceding paragraphs as if fully set forth herein.

53. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

54. An actual case or controversy between Taro and Glenmark exists such that the Court may entertain Taro's request for declaratory relief consistent with Article III of the United States Constitution.

55. Glenmark has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell and/or import its proposed generic Desoximetasone Topical Spray, 0.25%.

56. Glenmark's recent actions indicate that they do not intend to change their course of conduct.

57. Any manufacture, use, offer for sale, sale and/or importation of Glenmark's proposed generic Desoximetasone Topical Spray, 0.25%, prior to the expiration of the '780 patent will constitute direct infringement of the '780 patent.

58. Taro is entitled to a declaratory judgment that any manufacture, use, offer for sale, sale and/or importation of the proposed generic Desoximetasone Topical Spray, 0.25%, by Glenmark prior to the expiration of the '780 patent will constitute direct infringement of said patent.

59. On information and belief, despite having actual notice of the '780 patent, Glenmark continues to willfully, wantonly, and deliberately prepare to infringe the '780 patent in disregard of Taro's rights, making this case exceptional and entitling Taro to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT IV

(Declaratory Judgment of Infringement of the '780 Patent Under U.S.C. § 271(b) and (c) by Glenmark)

60. Taro incorporates each of the preceding paragraphs as if fully set forth herein.

61. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

62. An actual case or controversy between Taro and Glenmark exists such that the Court may entertain Taro's request for declaratory relief consistent with Article III of the United States Constitution.

63. Glenmark has actual knowledge of the '780 patent.

64. On information and belief, Glenmark became aware of the '780 patent no later than the date on which that patent was listed in the Orange Book.

65. On information and belief, Glenmark has acted with full knowledge of the '780 patent and without a reasonable basis for believing that Glenmark would not be liable for actively inducing or contributing to the infringement of the '780 patent.

66. The commercial manufacture, use, sale, offer for sale, and/or importation of Glenmark's proposed generic Desoximetasone Topical Spray, 0.25%, will induce the actual infringement of the '780 patent.

67. On information and belief, Glenmark knows or should know that their commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Desoximetasone Topical Spray, 0.25%, will actively induce the actual infringement of the '780 patent.

68. On information and belief, Glenmark will encourage another's infringement of the '780 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of their proposed generic Desoximetasone Topical Spray, 0.25%, which is covered by the claims of the '780 patent.

69. Glenmark's acts of infringement will be done with knowledge of the '780 patent and with the intent to encourage infringement.

70. The foregoing actions by Glenmark will constitute active inducement of infringement of the '780 patent.

71. On information and belief, Glenmark knows or should know that Glenmark's proposed generic Desoximetasone Topical Spray, 0.25%, will be especially made or especially adapted for use in an infringement of the '780 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

72. The commercial manufacture, use, sale, offer for sale, and/or importation of Glenmark's proposed generic Desoximetasone Topical Spray, 0.25%, will contribute to the actual infringement of the '780 patent.

73. On information and belief, Glenmark knows or should know that Glenmark's offer for sale, sale and/or importation of its proposed generic Desoximetasone Topical Spray, 0.25%, will contribute to the actual infringement of the '780 patent.

74. The foregoing actions by Glenmark will constitute contributory infringement of the '780 patent.

75. On information and belief, Glenmark intends to, and will, actively induce and contribute to the infringement of the '780 patent when ANDA No. 211760 is approved, and plan and intend to, and will, do so immediately and imminently upon final approval.

76. Taro is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Glenmark's proposed generic Desoximetasone Topical Spray, 0.25%, by Glenmark will induce and/or contribute to infringement of the '780 patent.

77. The commercial manufacture, use, offer for sale, sale and/or importation of Glenmark's proposed generic Desoximetasone Topical Spray, 0.25%, which will actively induce and/or contribute to infringement of the '780 patent, in violation of Taro's patent rights, will cause harm to Taro for which damages are inadequate.

78. Unless Glenmark is enjoined from actively inducing and contributing to the infringement of the '780 patent, Taro will suffer irreparable injury for which damages are an inadequate remedy.

79. On information and belief, despite having actual notice of the '780 patent, Glenmark continues to willfully, wantonly, and deliberately prepare to actively induce and/or

contribute to infringement of the '780 patent in disregard of Taro's rights, making this case exceptional and entitling Taro to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT V

(Declaratory Judgment of Infringement of the '624 Patent Under U.S.C. § 271(a) by Glenmark's Proposed Generic Desoximetasone Topical Spray, 0.25%)

80. Taro incorporates each of the preceding paragraphs as if fully set forth herein.

81. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

82. An actual case or controversy between Taro and Glenmark exists such that the Court may entertain Taro's request for declaratory relief consistent with Article III of the United States Constitution.

83. Glenmark has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell and/or import its proposed generic Desoximetasone Topical Spray, 0.25%.

84. Glenmark's recent actions indicate that they do not intend to change their course of conduct.

85. Any manufacture, use, offer for sale, sale and/or importation of Glenmark's proposed generic Desoximetasone Topical Spray, 0.25%, prior to the expiration of the '624 patent will constitute direct infringement of the '624 patent.

86. Taro is entitled to a declaratory judgment that any manufacture, use, offer for sale, sale and/or importation of the proposed generic Desoximetasone Topical Spray, 0.25%, by Glenmark prior to the expiration of the '624 patent will constitute direct infringement of said patent.

87. On information and belief, despite having actual notice of the '624 patent, Glenmark continues to willfully, wantonly, and deliberately prepare to infringe the '624 patent in

disregard of Taro's rights, making this case exceptional and entitling Taro to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT VI

(Declaratory Judgment of Infringement of the '624 Patent Under U.S.C. § 271(b) and (c) by Glenmark)

88. Taro incorporates each of the preceding paragraphs as if fully set forth herein.

89. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

90. An actual case or controversy between Taro and Glenmark exists such that the Court may entertain Taro's request for declaratory relief consistent with Article III of the United States Constitution.

91. Glenmark has actual knowledge of the '624 patent.

92. On information and belief, Glenmark became aware of the '624 patent no later than the date on which that patent was listed in the Orange Book.

93. On information and belief, Glenmark has acted with full knowledge of the '624 patent and without a reasonable basis for believing that Glenmark would not be liable for actively inducing or contributing to the infringement of the '624 patent.

94. The commercial manufacture, use, sale, offer for sale, and/or importation of Glenmark's proposed generic Desoximetasone Topical Spray, 0.25%, will induce the actual infringement of the '624 patent.

95. On information and belief, Glenmark knows or should know that their commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Desoximetasone Topical Spray, 0.25%, will actively induce the actual infringement of the '624 patent.

96. On information and belief, Glenmark will encourage another's infringement of the '624 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of their proposed generic Desoximetasone Topical Spray, 0.25%, which is covered by the claims of the '624 patent.

97. Glenmark's acts of infringement will be done with knowledge of the '624 patent and with the intent to encourage infringement.

98. The foregoing actions by Glenmark will constitute active inducement of infringement of the '624 patent.

99. On information and belief, Glenmark knows or should know that Glenmark's proposed generic Desoximetasone Topical Spray, 0.25%, will be especially made or especially adapted for use in an infringement of the '624 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

100. The commercial manufacture, use, sale, offer for sale, and/or importation of Glenmark's proposed generic Desoximetasone Topical Spray, 0.25%, will contribute to the actual infringement of the '624 patent.

101. On information and belief, Glenmark knows or should know that Glenmark's offer for sale, sale and/or importation of its proposed generic Desoximetasone Topical Spray, 0.25%, will contribute to the actual infringement of the '624 patent.

102. The foregoing actions by Glenmark will constitute contributory infringement of the '624 patent.

103. On information and belief, Glenmark intends to, and will, actively induce and contribute to the infringement of the '624 patent when ANDA No. 211760 is approved, and plan and intend to, and will, do so immediately and imminently upon final approval.

104. Taro is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Glenmark's proposed generic Desoximetasone Topical Spray, 0.25%, by Glenmark will induce and/or contribute to infringement of the '624 patent.

105. The commercial manufacture, use, offer for sale, sale and/or importation of Glenmark's proposed generic Desoximetasone Topical Spray, 0.25%, which will actively induce and/or contribute to infringement of the '624 patent, in violation of Taro's patent rights, will cause harm to Taro for which damages are inadequate.

106. Unless Glenmark is enjoined from actively inducing and contributing to the infringement of the '624 patent, Taro will suffer irreparable injury for which damages are an inadequate remedy.

107. On information and belief, despite having actual notice of the '624 patent, Glenmark continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '624 patent in disregard of Taro's rights, making this case exceptional and entitling Taro to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

PRAAYER FOR RELIEF

Plaintiffs respectfully pray for the following relief:

a. That judgment be entered that Glenmark has infringed the '780 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211760 under the FFDCA, and that the commercial manufacture, use, offer for sale, sale and/or importation of Glenmark's proposed generic Desoximetasone Topical Spray, 0.25%, prior to patent expiry will constitute an act of infringement of the '780 patent;

b. That judgment be entered that Glenmark has infringed the '624 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211760 under the FFDCA, and that the

commercial manufacture, use, offer for sale, sale and/or importation of Glenmark's proposed generic Desoximetasone Topical Spray, 0.25%, prior to patent expiry will constitute an act of infringement of the '624 patent;

c. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 211760 shall be a date that is not earlier than the expiration date of the '780 patent, including any extensions or exclusivities;

d. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 211760 shall be a date that is not earlier than the expiration date of the '624 patent, including any extensions or exclusivities;

e. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283 permanently enjoining Glenmark, Glenmark's officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in concert or participation with Glenmark or acting on Glenmark's behalf, from engaging in the commercial manufacture, use, offer to sale or sale within the United States, or importation into the United States, of any drug product covered by the '780 patent, including but not limited to Glenmark's proposed generic Desoximetasone Topical Spray, 0.25%, prior to the expiration date of such patent, including any extensions or exclusivities;

f. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283 permanently enjoining Glenmark, Glenmark's officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in concert or participation with Glenmark or acting on Glenmark's behalf, from engaging in the commercial manufacture, use, offer to sale or sale within the United States, or importation into the United States, of any drug product covered by the '624 patent, including but not limited to

Glenmark's proposed generic Desoximetasone Topical Spray, 0.25%, prior to the expiration date of such patent, including any extensions or exclusivities;

g. That a declaration be issued under 28 U.S.C. § 2201 that if Glenmark, Glenmark's officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in concert or participation with Glenmark or acting on Glenmark's behalf, engage in the commercial manufacture, use, offer for sale, sale and/or importation of Glenmark's generic Desoximetasone Topical Spray, 0.25%, prior to the expiration of the '780 patent, it will constitute infringement of said patent;

h. That a declaration be issued under 28 U.S.C. § 2201 that if Glenmark, Glenmark's officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in concert or participation with Glenmark or acting on Glenmark's behalf, engage in the commercial manufacture, use, offer for sale, sale and/or importation of Glenmark's generic Desoximetasone Topical Spray, 0.25%, prior to the expiration of the '624 patent, it will constitute infringement of said patent;

i. That damages or other monetary relief be awarded to Taro under 35 U.S.C. §§ 271(a), (b), (c) and (e)(4)(C), and/or 35 U.S.C. § 284 as appropriate;

j. That this is an exceptional case under 35 U.S.C. § 285 and that Plaintiffs be awarded reasonable attorneys' fees and costs; and

k. That this Court award such other and further relief as it may deem just and proper.

Dated: August 8, 2018

By: /Gregory D. Miller

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Pharmaceuticals North America, Inc.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

I hereby certify that the matter captioned *Taro Pharmaceuticals U.S.A. Inc., et al. v. Lupin Limited, et. al.*, which is pending in the District of New Jersey under docket number 2:18-cv-4225, is related to the matter in controversy because it involves infringement of the same patents.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: August 8, 2018

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

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

Dated: August 8, 2018

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