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*Attorneys for Plaintiffs, Taro Pharmaceuticals
U.S.A., Inc. and Taro Pharmaceuticals North 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,

v.

LUPIN LIMITED, LUPIN
PHARMACEUTICALS, INC., and LUPIN
ATLANTIS HOLDING SA,

Defendants.

C.A. No. 2:18-cv-04225-JMV-MF

JURY TRIAL DEMANDED

**PLAINTIFFS TARO PHARMACEUTICALS U.S.A., INC. AND TARO
PHARMACEUTICALS NORTH AMERICA, INC.'S FIRST AMENDED COMPLAINT
AGAINST LUPIN LIMITED, LUPIN PHARMACEUTICALS, INC., AND
LUPIN ATLANTIS HOLDING SA**

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

NATURE OF THE ACTION

1. This is an action under 35 U.S.C. § 271, *et. seq.*, 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*), relating to Taro’s commercially successful product, Topicort® (desoximetasone) Topical Spray, 0.25%. This action arises from Defendants’ making and selling a generic version of Topicort® (desoximetasone) Topical Spray, 0.25% prior to the expiration of the ’780 and ’624 patents pursuant to an Abbreviated New Drug Application (“ANDA”).

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 Lupin Ltd. is a corporation operating and existing under the laws of India, having a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India, and its registered office at Kalpataru Inspire 3rd Floor, Off Western Express Highway Santacruz (East), Mumbai 40055, India. Lupin Ltd. is one of the largest generic pharmaceutical companies in terms of global revenue.

5. On information and belief, LPI is a corporation operating and existing under the laws of Delaware, having a place of business at 111 South Calvert Street, 21st Floor, Baltimore, MD 21202.

6. On information and belief, LPI is a wholly owned subsidiary of Lupin Ltd.

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

8. On information and belief, Lupin Atlantis is a corporation organized and existing under the laws of Switzerland, having its principal place of business at Landis + Gyr-Strasse 1, 6300 Zug, Switzerland.

9. On information and belief, Lupin Atlantis is a wholly owned subsidiary of Lupin Ltd.

10. On information and belief, Lupin developed its generic Desoximetasone Topical Spray, 0.25% and prepared ANDA No. 208124 for submission. After receiving approval of its ANDA No. 208124, Lupin began to manufacture, sell, offer to sell, and/or import its generic Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml in the United States, including in this district.

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq.* Based on the facts alleged herein, this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338, and has personal jurisdiction over both Lupin Ltd. and LPI.

12. On information and belief, Lupin Ltd. directed its agents LPI and Lupin Atlantis to participate and collaborate in the research and development of the proposed generic Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml and in the preparation and filing of ANDA No. 208124.

13. On or about March 19, 2018, Lupin issued a press releasing stating, *inter alia*, the following:

Mumbai, Baltimore, March 19, 2018: Pharma major Lupin announced that it has received final approval for its Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml from the United States Food and Drug Administration (FDA) to market a generic version of Taro Pharmaceuticals U.S.A Inc.'s Topicort Topical Spray, 0.25%.

Lupin's Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml is the generic equivalent of Taro Pharmaceuticals U.S.A Inc.'s Topicort Topical Spray, 0.25%. It is a corticosteroid indicated for the treatment of plaque psoriasis in patients 18 years of age or older.

Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml had annual sales of approximately USD 19.5 million in the US (IQVIA MAT January 2018).¹

14. On information and belief, Lupin sought FDA approval, and issued the above-cited press release announcing that approval, because it intended to commit acts of patent infringement under 35 U.S.C. § 271(a), (b), and (c) through its manufacture, use, sell, and offer for sale of its generic Desoximetasone Topical Spray, 0.25% in New Jersey.

15. On information and belief, Lupin has commenced sales and marketing activities of its generic Desoximetasone Topical Spray, 0.25%, in the United States, including in this district.

16. This Court has personal jurisdiction over Lupin. Lupin avails itself of the benefits and protections of the laws of the State of New Jersey. For example, LPI is registered to do

¹ <http://www.lupin.com/lupin-receives-fda-approval-for-generic-topicort-topical-spray-0-25.php>

business in the State of New Jersey under Business ID Number 0100953673, and LPI is registered with the State of New Jersey as a manufacturer and wholesale distributor of drugs under Registration Numbers 5004060 and 5005159.

17. This Court also has personal jurisdiction over Lupin by virtue of its systematic and continuous contacts with the State of New Jersey. On information and belief, Lupin Ltd., LPI, Lupin Atlantis, and their affiliates manufacture generic pharmaceuticals at a facility located at 400 Campus Drive, Somerset, NJ. Lupin Ltd., LPI, and Lupin Atlantis sell, offer for sale, and distribute generic pharmaceuticals throughout the State of New Jersey.

18. On information and belief, Lupin 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 Lupin distributes throughout the United States.

19. On information and belief, Lupin's generic Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml is currently being marketed and distributed in New Jersey by Lupin, 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.

20. Lupin 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: *Lupin Ltd., et al. v. Merck, Sharp & Dohme Corp.*, Civil Action No. 3:10-cv-00683; *Senju Pharmaceutical Co., Ltd., et al. v. Lupin Ltd., et al.*, Civil Action No. 1:15-cv-00335; *Senju Pharmaceutical Co., Ltd., et al. v. Lupin Ltd., et al.*, Civil Action No. 1:14-cv-05144; *Janssen Products, L.P., et al. v. Lupin Ltd., et al.*, Civil Action No. 2:14-cv-01370; *Takeda Pharmaceutical Co. Ltd., et al. v. Lupin Ltd., et al.*, Civil Action No. 3:12-cv-07333; *AstraZeneca Pharmaceuticals LP, et al. v. Lupin Ltd., et al.*, Civil

Action No. 3:12-cv-06888; *Otsuka Pharmaceutical Co., Ltd. v. Lupin Ltd., et al.*, Civil Action No. 1:14-cv-07104; and *Prime European Therapeutics, S.p.A. v. Novel Labs., Inc., et al.*, Civil Action No. 3:17-cv-01944.

21. Venue is proper in this district under 28 U.S.C. §1400(b) because Lupin “committed an act of infringement” in this district and has a “regular place and established place of business” in this district. Lupin submitted an ANDA leading to FDA approval of its generic Desoximetasone Topical Spray, 0.25% and, having received approval, began to manufacture, sell, offer to sell, and/or import its generic Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml throughout the United States, including in this district. Lupin also has a “regular and established place of business” at its 150,000-square-foot facility at 400 Campus Drive, Somerset, New Jersey where Lupin manufactures about 3.5 billion standard units of pharmaceutical products.

BACKGROUND

The FDA Marketing Approval Process

22. 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.

23. 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.

24. 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).

25. 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).

26. 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

27. 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.

28. 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®

29. 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. Taro is the owner by assignment of all right, title, and interest in the ’780 patent.

30. 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. Taro is the owner by assignment of all right, title, and interest in the '624 patent.

COUNT I

(Infringement of the '624 Patent Under 35 U.S.C. § 271(a) by Lupin's Generic Desoximetasone Topical Spray, 0.25%)

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

32. On information and belief, Lupin has directly infringed and continues to directly infringe at least claims 1, 2, 3, 7, 10, 11, 13, 23, 24, 30, 31, and 32 of the '624 patent under 35 U.S.C. § 271(a) literally or under the doctrine of equivalents, by making, using, selling, offering to sell and/or importing its generic Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml.

33. The manufacture, use, offer for sale, sale and/or importation of Lupin's generic Desoximetasone Topical Spray, 0.25% prior to the expiration of the '624 patent constitutes direct infringement of at least claims 1, 2, 3, 7, 10, 11, 13, 23, 24, 30, 31, and 32 of the '624 patent.

34. As one, non-limiting example, Claim 1 of the '624 patent states as follows:

1. A liquid formulation comprising:
 - a) about 0.01 wt % to about 2.5 wt % desoximetasone;
 - b) about 10 wt % to about 70 wt % isopropyl myristate;
 - c) about 20 wt % to about 70 wt % C₂-C₄ alcohol; and
 - d) a stabilizing agent comprising a mixture of
 - (1) an oleaginous vehicle selected from the group consisting of mineral oil and light mineral oil and

- (2) a skin conditioning agent selected from one or more of the group consisting of
 - (i) a C₁₅-C₂₅ fatty alcohol present in the amount of about 0.5 wt % to about 10 wt %, and
 - (ii) an ester of glycerin and a C₁₅-C₂₅ fatty acid present in the amount of about 0.5 wt % to about 10 wt %.

35. On information and belief, each of the elements of claim 1 is present in Lupin's generic Desoximetasone Topical Spray, 0.25%.

36. As a result of Lupin's direct infringement of the '624 patent, Taro has suffered, and continues to suffer, damages, in an amount not yet determined, of at least a reasonable royalty and/or lost profits due to loss of sales, profits, and potential sales that Taro would have made but for Lupin's infringing acts.

37. Despite Lupin's knowledge of and notice of the '624 patent and its ongoing infringement, Lupin continues to manufacture, use, sell, offer for sale, and/or import its generic Desoximetasone Topical Spray, 0.25%, in a manner that infringes the '624 patent. Lupin lacks a justifiable belief that it does not infringe the '624 patent, or that the '624 patent is invalid, and has acted recklessly in its infringing activity, justifying an increase in the damages to be awarded to Taro up to three times the amount found or assessed, in accordance with 35 U.S.C. § 284.

38. The commercial manufacture, use, offer for sale, sale and/or importation of Lupin's generic Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml, in violation of Taro's patent rights, has caused and will continue to cause harm to Taro for which damages are inadequate.

39. Unless Lupin is enjoined from infringing the '624 patent, Taro will continue to suffer irreparable injury for which damages are an inadequate remedy.

40. Despite having actual notice of the '624 patent, Lupin continues to willfully, wantonly, and deliberately 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 II

(Infringement of the '624 Patent Under 35 U.S.C. § 271(b) and (c) by Lupin)

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

42. Lupin has actual knowledge of the '624 patent.

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

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

45. The commercial manufacture, use, sale, offer for sale, and/or importation of Lupin's generic Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml induces the actual infringement of the '624 patent.

46. On information and belief, Lupin knows or is willfully blind to the fact that their commercial manufacture, use, sale, offer for sale, and/or importation of its generic Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml actively induces the actual infringement of the '624 patent.

47. On information and belief, Lupin encourages another's infringement of the '624 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of their generic Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml, which is covered by the claims of the '624 patent.

48. Lupin's acts of infringement are done with knowledge of the '624 patent and with the intent to encourage infringement.

49. The foregoing actions by Lupin constitute active inducement of infringement of the '624 patent.

50. On information and belief, Lupin knows or is willfully blind to the fact that Lupin's proposed Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml is 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.

51. The commercial manufacture, use, sale, offer for sale, and/or importation of Lupin's generic Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml contributes to the actual infringement of the '624 patent.

52. On information and belief, Lupin knows or is willfully blind to the fact that Lupin's offer for sale, sale and/or importation of its generic Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml contributes to the actual infringement of the '624 patent.

53. The foregoing actions by Lupin constitute contributory infringement of the '624 patent.

54. As a result of Lupin's active induced and/or contributory infringement of the '624 patent, Taro has suffered, and continues to suffer, damages, in an amount not yet determined, of at least a reasonable royalty and/or lost profits due to loss of sales, profits, and potential sales that Taro would have made but for Lupin's infringing acts.

55. Despite Lupin's knowledge of and notice of the '624 patent and its ongoing infringement, Lupin continues to actively induce and/or contribute to the manufacture, use, sell, offer for sale, and/or import its generic Desoximetasone Topical Spray, 0.25%, in a manner that infringes the '624 patent. Lupin lacks a justifiable belief that it does not actively induce and/or contribute to the infringement the '624 patent, or that the '624 patent is invalid, and has acted recklessly in its infringing activity, justifying an increase in the damages to be awarded to Taro up to three times the amount found or assessed, in accordance with 35 U.S.C. § 284.

56. The commercial manufacture, use, offer for sale, sale and/or importation of Lupin's generic Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml, which actively induces and/or contributes to infringement of the '624 patent, in violation of Taro's patent rights, has caused and will continue to cause harm to Taro for which damages are inadequate.

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

58. On information and belief, despite having actual notice of the '624 patent, Lupin has and continues to willfully, wantonly, and deliberately 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.

COUNT III

(Infringement of the '780 Patent Under 35 U.S.C. § 271(a) by Lupin's Generic Desoximetasone Topical Spray, 0.25%)

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

60. On information and belief, Lupin has directly infringed and continues to directly infringe at least claims 1, 2, 3, 7, 8, 9, 10, 11, 13, 17, 29, 34, 35, 41, 42, 43, and 46 of the '780 patent under 35 U.S.C. § 271(a) literally or under the doctrine of equivalents, by making, using, selling, offering to sell and/or importing its generic Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml.

61. Any manufacture, use, offer for sale, sale and/or importation of Lupin's generic Desoximetasone Topical Spray, 0.25% prior to the expiration of the '780 patent constitutes direct infringement of at least claims 1, 2, 3, 7, 8, 9, 10, 11, 13, 17, 29, 34, 35, 41, 42, 43, and 46 of the '780 patent.

62. As one, non-limiting example, Claim 1 of the '780 patent states as follows:

1. A liquid formulation comprising:
 - a) about 0.01 wt % to about 2.5 wt % desoximetasone;
 - b) about 10 wt % to about 70 wt % isopropyl myristate;
 - c) about 20 wt % to about 70 Wt % C₂-C₄ alcohol; and
 - d) a stabilizing agent comprising a mixture of
 - (a) an oleaginous vehicle selected from the group consisting of mineral oil and light mineral oil present in the amount of about 10 wt % to about 60 wt % and
 - (b) a skin conditioning agent selected from one or more of the group consisting of
 - (i) a C₁₅-C₂₅ fatty alcohol present in the amount of about 0.5 wt % to about 10 wt % and
 - (ii) an ester of glycerin and a C₁₅-C₂₅ fatty acid present in the amount of about 0.5 wt % to about 10 wt %.

63. On information and belief, each of the elements of claim 1 is present in Lupin's generic Desoximetasone Topical Spray, 0.25%.

64. As a result of Lupin's direct infringement of the '780 patent, Taro has suffered, and continues to suffer, damages, in an amount not yet determined, of at least a reasonable royalty and/or lost profits due to loss of sales, profits, and potential sales that Taro would have made but for Lupin's infringing acts.

65. Despite Lupin's knowledge of and notice of the '780 patent and its ongoing infringement, Lupin continue to manufacture, use, sell, offer for sale, and/or import its generic Desoximetasone Topical Spray, 0.25%, in a manner that infringes the '780 patent. Lupin lacks a justifiable belief that it does not infringe the '780 patent, or that the '780 patent is invalid, and has acted recklessly in its infringing activity, justifying an increase in the damages to be awarded to Taro up to three times the amount found or assessed, in accordance with 35 U.S.C. § 284.

66. The commercial manufacture, use, offer for sale, sale and/or importation of Lupin's generic Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml, in violation of Taro's patent rights, has caused and will continue to cause harm to Taro for which damages are inadequate.

67. Unless Lupin is enjoined from infringing the '780 patent, Taro will continue to suffer irreparable injury for which damages are an inadequate remedy

68. Despite having actual notice of the '780 patent, Lupin continues to willfully, wantonly, and deliberately 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

(Infringement of the '780 Patent Under 35 U.S.C. § 271(b) and (c) by Lupin)

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

70. Lupin has actual knowledge of the '780 patent.

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

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

73. The commercial manufacture, use, sale, offer for sale, and/or importation of Lupin's generic Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml induces the actual infringement of the '780 patent.

74. On information and belief, Lupin knows or is willfully blind to the fact that their commercial manufacture, use, sale, offer for sale, and/or importation of its generic Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml actively induces the actual infringement of the '780 patent.

75. On information and belief, Lupin encourages another's infringement of the '780 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation

of their generic Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml, which is covered by the claims of the '780 patent.

76. Lupin's acts of infringement are done with knowledge of the '780 patent and with the intent to encourage infringement.

77. The foregoing actions by Lupin constitute active inducement of infringement of the '780 patent.

78. On information and belief, Lupin knows or is willfully blind to the fact that Lupin's proposed Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml is 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.

79. The commercial manufacture, use, sale, offer for sale, and/or importation of Lupin's generic Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml contributes to the actual infringement of the '780 patent.

80. On information and belief, Lupin knows or is willfully blind to the fact that Lupin's offer for sale, sale and/or importation of its generic Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml contributes to the actual infringement of the '780 patent.

81. The foregoing actions by Lupin constitute contributory infringement of the '780 patent.

82. As a result of Lupin's active induced and/or contributory infringement of the '780 patent, Taro has suffered, and continues to suffer, damages, in an amount not yet determined, of at least a reasonable royalty and/or lost profits due to loss of sales, profits, and potential sales that Taro would have made but for Lupin's infringing acts.

83. Despite Lupin's knowledge of and notice of the '780 patent and its ongoing infringement, Lupin continues to actively induce and/or contribute to the manufacture, use, sell,

offer for sale, and/or import its generic Desoximetasone Topical Spray, 0.25%, in a manner that infringes the '780 patent. Lupin lacks a justifiable belief that it does not actively induce and/or contribute to the infringement the '780 patent, or that the '780 patent is invalid, and has acted recklessly in its infringing activity, justifying an increase in the damages to be awarded to Taro up to three times the amount found or assessed, in accordance with 35 U.S.C. § 284.

84. The commercial manufacture, use, offer for sale, sale and/or importation of Lupin's generic Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml, which actively induces and/or contributes to infringement of the '780 patent, in violation of Taro's patent rights, has caused and will continue to cause harm to Taro for which damages are inadequate.

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

86. On information and belief, despite having actual notice of the '780 patent, Lupin has and continues to willfully, wantonly, and deliberately 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.

PRAYER FOR RELIEF

Plaintiffs respectfully pray for the following relief:

- a. A finding that Lupin has infringed one or more claims of the '624 patent under 35 U.S.C. § 271(a), (b), and/or (c) and a final judgment incorporating the same;
- b. A finding that Lupin has infringed one or more claims of the '780 patent under 35 U.S.C. § 271(a), (b), and/or (c) and a final judgment incorporating the same;
- c. A finding that Lupin's infringement of the '624 patent has been and is willful;

- d. A finding that Lupin's infringement of the '780 patent has been and is willful;
- e. That an injunction be issued under 35 U.S.C. § 283 permanently enjoining Lupin, Lupin's officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in concert or participation with Lupin or acting on Lupin'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 Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml, prior to the expiration date of such patent, including any extensions or exclusivities;
- f. That an injunction be issued under 35 U.S.C. § 283 permanently enjoining Lupin, Lupin's officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in concert or participation with Lupin or acting on Lupin'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 Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml, prior to the expiration date of such patent, including any extensions or exclusivities;
- g. That damages or other monetary relief be awarded to Taro under 35 U.S.C. §§ 271(a), (b), (c) and/or 35 U.S.C. § 284 as appropriate;
- h. That this is an exceptional case under 35 U.S.C. § 285 and that Plaintiffs be awarded reasonable attorneys' fees and costs; and
- i. That this Court award such other and further relief as it may deem just and proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury of any issue so triable as of right pursuant to Rule 38(b) of the Federal Rules of Civil Procedure.

Dated: September 28, 2018

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby 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: September 28, 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: September 28, 2018

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