

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

LEO PHARMA A/S, LEO PHARMA INC.,)
and FOAMIX PHARMACEUTICALS LTD.,)
)
)
Plaintiffs,)
)
)
v.) C.A. No. _____
)
)
TARO PHARMACEUTICALS U.S.A., INC.,)
and TARO PHARMACEUTICAL)
INDUSTRIES LTD.,)
)
)
Defendants.)
)

COMPLAINT

Plaintiffs LEO Pharma A/S, LEO Pharma Inc. (collectively, “LEO”), and Foamix Pharmaceuticals Ltd. (“Foamix,” and collectively with LEO, “Plaintiffs”), by their attorneys, for their Complaint, allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code that arises out of the submission by defendants Taro Pharmaceuticals U.S.A., Inc., and Taro Pharmaceutical Industries Limited (collectively, “Taro”) of Abbreviated New Drug Application (“ANDA”) No. 212581 to the U.S. Food and Drug Administration (“FDA”) seeking approval to manufacture and sell a generic version of LEO’s FINACEA® (azelaic acid) Foam (“FINACEA® Foam”) prior to the expiration of U.S. Patent No. 7,700,076 (“the ’076 patent”), U.S. Patent No. 8,435,498 (“the ’498 patent”), U.S. Patent No. 8,722,021 (“the ’021 patent”), U.S. Patent No. 8,900,554 (“the ’554 patent”), U.S. Patent No. 9,211,259 (“the ’259 patent”), U.S. Patent No. 9,265,725 (“the ’725 patent”), and U.S. Patent No. 10,117,812 (“the ’812 patent”).

PARTIES

2. Plaintiff LEO Pharma A/S is a corporation organized and existing under the laws of the Kingdom of Denmark, with a place of business at Industriparken 55, DK-2750, Ballerup, Denmark. LEO Pharma A/S holds New Drug Application (“NDA”) No. 207071 on FINACEA® (active ingredient 15% azelaic acid) Foam.

3. Plaintiff LEO Pharma Inc. is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 7 Giralda Farms, 2nd Floor, Madison, NJ 07940.

4. Plaintiff Foamix Pharmaceuticals Limited is a corporation organized and existing under the laws of the State of Israel, with a place of business at 2 Holzman Street, Weizmann Science Park, Rehovot 7670402, Israel.

5. Upon information and belief, defendant Taro Pharmaceutical Industries Limited is a corporation organized and existing under the laws of the State of Israel and headquartered in Haifa Bay, Israel. On further information and belief, Taro Pharmaceutical Industries Limited has a principal place of business at 14 Hakitor Street, P.O. Box 10347, Haifa Bay 2624761.

6. Upon information and belief, defendant Taro Pharmaceutical U.S.A., Inc., is a corporation organized and existing under the laws of the State of New York with its principal place of business at 3 Skyline Drive, Hawthorne, New York, 10532. On further information and belief, Taro Pharmaceuticals U.S.A., Inc. is a wholly-owned subsidiary of Taro Pharmaceutical Industries Limited.

7. Upon information and belief, and consistent with its practice with respect to other generic products, following any FDA approval of ANDA No. 212581, Taro will distribute and

sell its generic product throughout the United States through its own actions and through the actions of its agents and affiliates, including, but not limited to Taro Pharmaceuticals U.S.A.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

9. This Court has personal jurisdiction over Defendants because defendant Taro Pharmaceuticals U.S.A. is a corporation organized under the laws of the State of New York with its principal place of business at 3 Skyline Drive, Hawthorne, New York, 10532.

10. Additionally, upon information and belief, Taro is in the business of, among other things, developing, manufacturing, marketing, importing, and selling generic pharmaceutical products throughout the United States, including in the Southern District of New York.

11. Upon information and belief, Taro, directly or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States, including the State of New York and this judicial district, and, if approved, Taro's generic version of FINACEA® Foam will be marketed and sold in the State of New York and this judicial district.

12. Upon information and belief, Taro purposefully has conducted, and continues to conduct, business in this District.

13. Upon information and belief, Taro has, directly or through intermediaries, committed acts within this District such that the existence of jurisdiction would not offend traditional notions of fair play and justice.

14. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and § 1400(b).

BACKGROUND

15. FINACEA® Foam (active ingredient 15% azelaic acid) is a topical prescription medicine used to treat the inflammatory papules and pustules of mild to moderate rosacea.

16. The '076 patent, entitled "Penetrating Pharmaceutical Foam" (Exhibit A hereto), was duly and legally issued on April 20, 2010, to Foamix Ltd., as assignee, and subject to the exclusive license referenced herein. The '076 patent was thereafter assigned to Foamix Pharmaceuticals Ltd. on June 1, 2014. FINACEA® Foam and the use thereof are covered by one or more claims of the '076 patent, which has been listed in connection with FINACEA® Foam in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book."

17. The '498 patent, entitled "Penetrating Pharmaceutical Foam" (Exhibit B hereto), was duly and legally issued on May 7, 2013, to Foamix Ltd., as assignee, and subject to the exclusive license referenced herein. The '498 patent was thereafter assigned to Foamix Pharmaceuticals Ltd. on June 1, 2014. FINACEA® Foam and the use thereof are covered by one or more claims of the '498 patent, which has been listed in connection with FINACEA® Foam in the Orange Book.

18. The '021 patent, entitled "Foamable Carriers" (Exhibit C hereto), was duly and legally issued on May 13, 2014, to Foamix Ltd., as assignee, and subject to the exclusive license referenced herein. The '021 patent was thereafter assigned to Foamix Pharmaceuticals Ltd. on June 1, 2014. FINACEA® Foam and the use thereof are covered by one or more claims of the '021 patent, which has been listed in connection with FINACEA® Foam in the Orange Book.

19. The '554 patent, entitled "Foamable Composition and Uses Thereof" (Exhibit D hereto), was duly and legally issued on December 2, 2014, to Foamix Pharmaceuticals Ltd., as assignee, and subject to the exclusive license referenced herein. FINACEA® Foam and the use

thereof are covered by one or more claims of the '554 patent, which has been listed in connection with FINACEA® Foam in the Orange Book.

20. The '259 patent, entitled "Antibiotic Kit and Composition and Uses Thereof" (Exhibit E hereto), was duly and legally issued on December 15, 2015, to Foamix Pharmaceuticals Ltd., as assignee, and subject to the exclusive license referenced herein. FINACEA® Foam and the use thereof are covered by one or more claims of the '259 patent, which has been listed in connection with FINACEA® Foam in the Orange Book.

21. The '725 patent, entitled "Dicarboxylic Acid Foamable Vehicle and Pharmaceutical Compositions Thereof" (Exhibit F hereto), was duly and legally issued on February 23, 2016, to Foamix Pharmaceuticals Ltd., as assignee, and subject to the exclusive license referenced herein. FINACEA® Foam and the use thereof are covered by one or more claims of the '725 patent, which has been listed in connection with FINACEA® Foam in the Orange Book.

22. The '812 patent, entitled "Foamable Composition Combining a Polar Solvent and a Hydrophobic Carrier" (Exhibit G hereto), was duly and legally issued on November 6, 2018, to Foamix Pharmaceuticals Ltd., as assignee, and subject to the exclusive license referenced herein. FINACEA® Foam and the use thereof are covered by one or more claims of the '812 patent. FINACEA® Foam and the use thereof are covered by one or more claims of the '812 patent, which has been listed in connection with FINACEA® Foam in the Orange Book.

23. On December 8, 2006, Intendis GmbH ("Intendis") took an exclusive license to the Finacea® Foam Product covered by certain Foamix patents and patent applications, including those applications which ultimately led to the issuance of the '076 patent, the '498 patent, the '021 patent, the '554 patent, the '259 patent, the '725 patent, and the '812 patent ("Foamix

patents”). In December 2013, Intendis and Bayer Pharma AG, the parent of Intendis, entered into a business lease agreement providing, among other things, for the substitution of Intendis by Bayer Pharma AG in existing agreements. Thus, effective January 1, 2014, the exclusive license to the Foamix patents was assigned to Bayer Pharma AG. Thereafter, effective as of January 1, 2017, the exclusive license was assigned to Bayer AG, the parent of Bayer Pharma AG.

24. In September 2018, Bayer AG sold its prescription dermatology business to LEO Pharma A/S. In connection with that sale, LEO Pharma A/S acquired Bayer AG’s rights in the Foamix license agreement. On September 18, 2018, LEO Pharma A/S granted LEO Pharma Inc. a sublicense to the Foamix license.

25. LEO Pharma A/S is the holder of New Drug Application No. 207071 for FINACEA® Foam, which has been approved by the FDA.

26. On or around December 21, 2018, LEO and Foamix, respectively, received a notice letter dated December 20, 2018, from Taro stating that Taro had submitted to the FDA ANDA No. 212581 for an azelaic acid foam composition containing 15% azelaic acid (“Taro’s ANDA Product”) (“First Notice Letter”). Taro’s ANDA Product is a drug product that is a generic version of FINACEA® Foam. In its First Notice Letter, Taro indicated that, in connection with its ANDA No. 212581, Taro had filed Paragraph IV Certifications with respect to each of the ’076 patent, the ’498 patent, the ’021 patent, the ’554 patent, the ’259 patent, and the ’725 patent.

27. On or around January 21, 2019, LEO and Foamix, respectively, received a notice letter dated January 18, 2019, from Taro stating that Taro had submitted to the FDA ANDA No. 212581 for an azelaic acid foam composition containing 15% azelaic acid (“Second Notice Letter”). Taro’s ANDA Product is a drug product that is a generic version of FINACEA® Foam.

In its Second Notice Letter, Taro indicated that, in connection with its ANDA No. 212581, Taro had filed Paragraph IV Certifications with respect to the '812 patent.

28. Taro seeks to obtain approval of ANDA No. 212581 under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Taro's ANDA Product prior to the expiration of the '076 patent, the '498 patent, the '021 patent, the '554 patent, the '259 patent, the '725 patent, and the '812 patent.

29. LEO requested confidential access to materials necessary to ascertain whether Taro infringed the relevant patent, including Taro's ANDA, the Drug Master File, samples of its ANDA product, and records of testing conducted on its ANDA product. Counsel for Taro and counsel for LEO were unable to agree on terms under which LEO could review all of the materials requested and Taro refused to produce the documents and data.

30. This action is being commenced before the expiration of forty-five days from the receipt of the First Notice Letter.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 7,700,076

31. Plaintiffs fully incorporate each of the preceding paragraphs 1–30 as if fully set forth herein.

32. Upon information and belief, Taro's ANDA Product infringes one or more claims of the '076 patent either literally or under the doctrine of equivalents.

33. As an example, claim 11 of the '076 patent recites an oil in water foamable composition comprising:

- a. about 5 to about 50% by weight of composition of a liquid, non-volatile hydrophobic solvent;

- b. about 0.1 to 5% by weight of a surface-active agent selected from the group consisting of a polysorbate, a polyoxyethylene fatty acid ester, a polyoxyethylene alkyl ether, a sucrose ester, a partial ester of sorbitol, a partial ester of sorbitol anhydride, sodium methyl cocoyl taurate, sodium methyl oleoyl taurate, sodium lauryl sulfate, triethanolamine lauryl sulfate, a betaine, a mono-, di- or tri-ester of sucrose with food fatty acids (sucrose esters), a monoglyceride, a diglyceride, polyoxyethylene (20) sorbitan monostearate, polyoxyethylene (20) sorbitan monooleate, Myrj 45 (Polyoxyethylene (8) Stearate), Myrj 49 (polyoxyethylene (20) stearate), Myrj 59 (polyoxoethylene (100) stearate), a polyoxyethylene cetyl ether, a polyoxyethylene palmityl ether, a polyethylene oxide hexadecyl ether, Brij 52 (polyoxyethylene (2) cetyl ether), Brij 56 (polyoxyethylene (10) cetyl ether), sorbitan monolaurate, isoceteth 20, cocamidopropyl betaine, and Myrj 52 (polyoxyethylene 40 stearate);
- c. about 0.1 to 5% by weight of a gelling agent;
- d. a therapeutic enhancer selected from the group consisting of propylene glycol, butylene glycols, glycerol, pentaerythritol, sorbitol, mannitol, oligosaccharides, dimethyl isosorbide, monooleate of ethoxylated glycerides having about 8 to 10 ethylene oxide units, polyethylene glycol 200-600, transcutol, glycofurool and cyclodextrins; and
- e. a liquefied or compressed gas propellant at a concentration of about 3% to about 18% by weight of the total composition;

wherein the composition contains no more than 7.5% of methyl alcohol, ethyl alcohol, isopropyl alcohol, butyl alcohol, or mixtures thereof; and

wherein said composition is a stable emulsion in its predispensed state and forms a breakable foam upon dispensing.

34. Upon information and belief, Taro's ANDA Product infringes claim 11 of the '076 patent literally or under the doctrine of equivalents.

35. Taro's submission of ANDA No. 212581 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Taro's ANDA Product prior to the expiration of the '076 patent was an act of infringement of the '076 patent under 35 U.S.C. § 271(e)(2)(A).

36. Upon information and belief, Taro intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Taro's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 212581, *i.e.*, prior to the expiration of the '076 patent.

37. Upon information and belief, Taro has knowledge of the claims of the '076 patent. Notwithstanding this knowledge, Taro has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Taro's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 212581.

38. Upon information and belief, Taro plans and intends to, and will, actively induce infringement of the '076 patent when ANDA No. 212581 is approved, and plans and intends to, and will, do so after approval.

39. Upon information and belief, Taro knows that Taro's ANDA Product is especially made or adapted for use in infringing the '076 patent, and that Taro's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Taro plans and intends

to, and will, contribute to infringement of the '076 patent immediately and imminently upon approval of ANDA No. 212581.

40. The foregoing actions by Taro constitute and/or will constitute infringement of the '076 patent, active inducement of infringement of the '076 patent, and contributing to the infringement by others of the '076 patent.

41. Unless Taro is enjoined from infringing the '076 patent, actively inducing infringement of the '076 patent, and contributing to the infringement by others of the '076 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II – INFRINGEMENT OF U.S. PATENT NO. 8,435,498

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

43. Upon information and belief, Taro's ANDA Product and its proposed labeling directing use of Taro's ANDA Product infringe one or more claims of the '498 patent either literally or under the doctrine of equivalents.

44. As an example, claim 1 of the '498 patent recites a method of skin or mucosal surface application comprising spreading or collapsing a breakable thermally stable foam by mechanical force at or about a target site of a subject, the breakable thermally stable foam obtained by dispensing a foamable emulsion composition comprising:

- a. about 0.1 to about 5% by weight of a surface-active agent;
- b. about 5 to about 50% by weight of a liquid, non-volatile hydrophobic solvent;
- c. about 0.1 to about 5% by weight of a gelling agent; and
- d. a component selected from the group consisting of urea, a hydroxy acid, a therapeutic enhancer, and mixtures of two or more thereof;

- e. water; and
- f. a liquefied or a compressed gas propellant;

wherein the foamable emulsion composition contains no more than 7.5% by weight methyl alcohol, ethyl alcohol, isopropyl alcohol, butyl alcohol, or mixtures thereof.

45. Upon information and belief, Taro's ANDA Product and its proposed labeling directing use of Taro's ANDA Product infringe claim 1 of the '498 patent either literally or under the doctrine of equivalents.

46. Taro's submission of ANDA No. 212581 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Taro's ANDA Product prior to the expiration of the '498 patent was an act of infringement of the '498 patent under 35 U.S.C. § 271(e)(2)(A).

47. Upon information and belief, Taro intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Taro's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 212581, *i.e.*, prior to the expiration of the '498 patent.

48. Upon information and belief, Taro has knowledge of the claims of the '498 patent. Notwithstanding this knowledge, Taro has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Taro's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 212581.

49. Upon information and belief, Taro plans and intends to, and will, actively induce infringement of the '498 patent when ANDA No. 212581 is approved, and plans and intends to, and will, do so after approval.

50. Upon information and belief, Taro knows that Taro's ANDA Product is especially made or adapted for use in infringing the '498 patent, and that Taro's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Taro plans and intends to, and will, contribute to infringement of the '498 patent immediately and imminently upon approval of ANDA No. 212581.

51. The foregoing actions by Taro constitute and/or will constitute infringement of the '498 patent, active inducement of infringement of the '498 patent, and contributing to the infringement by others of the '498 patent.

52. Unless Taro is enjoined from infringing the '498 patent, actively inducing infringement of the '498 patent, and contributing to the infringement by others of the '498 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT III – INFRINGEMENT OF U.S. PATENT NO. 8,722,021

53. Plaintiffs fully incorporate each of the preceding paragraphs 1–52 as if fully set forth herein.

54. Upon information and belief, Taro's ANDA Product infringes one or more claims of the '021 patent either literally or under the doctrine of equivalents.

55. In its First Notice Letter, Taro does not contest infringement as to claims 1–4, 7–17 and 23 of the '021 patent.

56. As an example, claim 1 of the '021 patent recites a foamable composition comprising a carrier and a liquefied or a compressed gas propellant, the carrier comprising:

- a. about 0.1% to about 5% by weight of the carrier of the surface-active agent;
- b. about 2% to about 75% by weight of the carrier of an organic solvent selected from the group consisting of an emollient, a polar solvent, an oil, and mixtures thereof;
- c. about 0.01% to about 5% by weight of the carrier of at least one polymeric agent selected from the group consisting of a bioadhesive agent, a gelling agent, a film forming agent, and a phase change agent; and
- d. water;

wherein upon release from a foam dispenser, a foam is produced; and

wherein the foam remains stable as a foam for at least 60 seconds at 37° C.

57. Upon information and belief, Taro's ANDA Product infringes claim 1 of the '021 patent literally or under the doctrine of equivalents.

58. Taro's submission of ANDA No. 212581 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Taro's ANDA Product prior to the expiration of the '021 patent was an act of infringement of the '021 patent under 35 U.S.C. § 271(e)(2)(A).

59. Upon information and belief, Taro intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Taro's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 212581, *i.e.*, prior to the expiration of the '021 patent.

60. Upon information and belief, Taro has knowledge of the claims of the '021 patent. Notwithstanding this knowledge, Taro has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Taro's

ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 212581.

61. Upon information and belief, Taro plans and intends to, and will, actively induce infringement of the '021 patent when ANDA No. 212581 is approved, and plans and intends to, and will, do so after approval.

62. Upon information and belief, Taro knows that Taro's ANDA Product is especially made or adapted for use in infringing the '021 patent, and that Taro's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Taro plans and intends to, and will, contribute to infringement of the '021 patent immediately and imminently upon approval of ANDA No. 212581.

63. The foregoing actions by Taro constitute and/or will constitute infringement of the '021 patent, active inducement of infringement of the '021 patent, and contributing to the infringement by others of the '021 patent.

64. Unless Taro is enjoined from infringing the '021 patent, actively inducing infringement of the '021 patent, and contributing to the infringement by others of the '021 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT IV – INFRINGEMENT OF U.S. PATENT NO. 8,900,554

65. Plaintiffs fully incorporate each of the preceding paragraphs 1–64 as if fully set forth herein.

66. Upon information and belief, Taro's ANDA Product infringes one or more claims of the '554 patent either literally or under the doctrine of equivalents.

67. In its First Notice Letter, Taro does not contest infringement as to claims 1, 3–5, 7–16, and 18–20 of the '554 patent.

68. As an example, claim 1 of the '554 patent recites a composition comprising a foamable composition and a propellant, the foamable composition comprising:
- a. an active agent;
 - b. at least one organic carrier selected from the group consisting of a hydrophobic organic carrier, an organic polar solvent, an emollient, and mixtures of any two or more thereof, at a concentration of about 2% to about 50% by weight of the foamable composition;
 - c. a surface active agent; and
 - d. water;

wherein the propellant is a liquefied or compressed gas propellant at a concentration of about 3% to about 25% by weight of the foamable composition;

wherein the composition is stored in a container and upon release form a breakable foam that collapses upon application of shear force; and

wherein the foamable composition comprises less than 5% or about 5% by weight of the foamable composition of lower alcohols.

69. Upon information and belief, Taro's ANDA Product infringes claim 1 of the '554 patent literally or under the doctrine of equivalents.

70. Taro's submission of ANDA No. 212581 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Taro's ANDA Product prior to the expiration of the '554 patent was an act of infringement of the '554 patent under 35 U.S.C. § 271(e)(2)(A).

71. Upon information and belief, Taro intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Taro's ANDA Product and the

proposed labeling therefor immediately and imminently upon approval of ANDA No. 212581, *i.e.*, prior to the expiration of the '554 patent.

72. Upon information and belief, Taro has knowledge of the claims of the '554 patent. Notwithstanding this knowledge, Taro has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Taro's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 212581.

73. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Taro's ANDA Product would infringe one or more claims of the '554 patent, either literally or under the doctrine of equivalents.

74. Upon information and belief, Taro plans and intends to, and will, actively induce infringement of the '554 patent when ANDA No. 212581 is approved, and plans and intends to, and will, do so after approval.

75. Upon information and belief, Taro knows that Taro's ANDA Product is especially made or adapted for use in infringing the '554 patent, and that Taro's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Taro plans and intends to, and will, contribute to infringement of the '554 patent immediately and imminently upon approval of ANDA No. 212581.

76. The foregoing actions by Taro constitute and/or will constitute infringement of the '554 patent, active inducement of infringement of the '554 patent, and contributing to the infringement by others of the '554 patent. Unless Taro is enjoined from infringing the '554 patent, actively inducing infringement of the '554 patent, and contributing to the infringement by

others of the '554 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT V – INFRINGEMENT OF U.S. PATENT NO. 9,211,259

77. Plaintiffs fully incorporate each of the preceding paragraphs 1–76 as if fully set forth herein.

78. Upon information and belief, Taro's ANDA Product and its proposed labeling directing use of Taro's ANDA Product infringe one or more claims of the '259 patent either literally or under the doctrine of equivalents.

79. As an example, claim 1 of the '259 patent recites a method of treating or alleviating disorders of a skin, body cavity or mucosal surface, wherein the disorder involves inflammation as one of its etiological factors, the method comprising:

- a. releasing a foamable composition from an aerosol container to form an expanded thermally stable foam that collapses upon application of mechanical force, said foamable composition comprising a propellant and a composition, said composition comprising:
 - i. an antibiotic agent;
 - ii. a therapeutically active oil comprising about 10% to about 50% by weight of the composition of a capric/caprylic triglyceride;
 - iii. a surface-active agent;
 - iv. about 0.01% to about 5% by weight of the composition of at least one polymeric additive selected from the group consisting of a bioadhesive agent, a gelling agent, a film forming agent and a phase change agent; and
 - v. water;

- wherein the propellant comprises a liquefied or compressed gas propellant at a concentration of about 3% to about 25% by weight of the foamable composition
- b. administering the foam to a target area having a disorder of the skin, body cavity or mucosa; and
- c. collapsing the foam by applying mechanical force, wherein the foam is absorbed onto the target area,

wherein the antibiotic agent is administered in a therapeutically effective amount; wherein the composition contains less than 5% by weight of the composition of short chain alcohols having up to 5 carbon atoms in their carbon chain skeleton and one hydroxyl group; and

wherein the composition is a thermally stable breakable foam.

80. Upon information and belief, Taro's ANDA Product and its proposed labeling directing use of Taro's ANDA Product infringe claim 1 of the '259 patent either literally or under the doctrine of equivalents.

81. Taro's submission of ANDA No. 212581 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Taro's ANDA Product prior to the expiration of the '259 patent was an act of infringement of the '259 patent under 35 U.S.C. § 271(e)(2)(A).

82. Upon information and belief, Taro intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Taro's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 212581, *i.e.*, prior to the expiration of the '259 patent.

83. Upon information and belief, Taro has knowledge of the claims of the '259 patent. Notwithstanding this knowledge, Taro has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Taro's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 212581.

84. Upon information and belief, Taro plans and intends to, and will, actively induce infringement of the '259 patent when ANDA No. 212581 is approved, and plans and intends to, and will, do so after approval.

85. Upon information and belief, Taro knows that Taro's ANDA Product is especially made or adapted for use in infringing the '259 patent, and that Taro's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Taro plans and intends to, and will, contribute to infringement of the '259 patent immediately and imminently upon approval of ANDA No. 212581.

86. The foregoing actions by Taro constitute and/or will constitute infringement of the '259 patent, active inducement of infringement of the '259 patent, and contributing to the infringement by others of the '259 patent.

87. Unless Taro is enjoined from infringing the '259 patent, actively inducing infringement of the '259 patent, and contributing to the infringement by others of the '259 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT VI – INFRINGEMENT OF U.S. PATENT NO. 9,265,725

88. Plaintiffs fully incorporate each of the preceding paragraphs 1–87 as if fully set forth herein.

89. Upon information and belief, Taro's ANDA Product infringes one or more claims of the '725 patent either literally or under the doctrine of equivalents.

90. As an example, claim 1 of the '725 patent recites a foamable composition comprising a foamable carrier and a propellant, the foamable carrier comprising:

- a. about 15% by weight of an azelaic acid;
- b. about 11% by weight of medium-chain triglycerides;
- c. about 11% by weight of propylene glycol;
- d. about 5% by weight of dimethyl isosorbide;
- e. about 3% by weight of PEG-40 stearate;
- f. about 1% by weight of a cetostearyl alcohol;
- g. about 1% by weight of polysorbate 80;
- h. about 0.5% by weight of a monoglyceride, a diglyceride, or a combination;
- i. about 0.3% by weight of a xanthan gum;
- j. about 0.1% by weight of methylcellulose;
- k. about 0.1% by weight of a benzoic acid;
- l. water;
- m. sodium hydroxide; and

wherein the pH of said foamable carrier is about 4.5–5.3; and

wherein the propellant is at a concentration of about 3% to about 25% by weight of the total composition.

91. Upon information and belief, Taro's ANDA Product infringes claim 1 of the '725 patent literally or under the doctrine of equivalents.

92. Taro's submission of ANDA No. 212581 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Taro's ANDA Product prior to the expiration of the '725 patent was an act of infringement of the '725 patent under 35 U.S.C. § 271(e)(2)(A).

93. Upon information and belief, Taro intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Taro's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 212581, *i.e.*, prior to the expiration of the '725 patent.

94. Upon information and belief, Taro has knowledge of the claims of the '725 patent. Notwithstanding this knowledge, Taro has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Taro's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 212581.

95. Upon information and belief, Taro plans and intends to, and will, actively induce infringement of the '725 patent when ANDA No. 212581 is approved, and plans and intends to, and will, do so after approval.

96. Upon information and belief, Taro knows that Taro's ANDA Product is especially made or adapted for use in infringing the '725 patent, and that Taro's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Taro plans and intends to, and will, contribute to infringement of the '725 patent immediately and imminently upon approval of ANDA No. 212581.

97. The foregoing actions by Taro constitute and/or will constitute infringement of the '725 patent, active inducement of infringement of the '725 patent, and contributing to the infringement by others of the '725 patent.

98. Unless Taro is enjoined from infringing the '725 patent, actively inducing infringement of the '725 patent, and contributing to the infringement by others of the '725 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT VII –INFRINGEMENT OF U.S. PATENT NO. 10,117,812

99. Plaintiffs fully incorporate each of the preceding paragraphs 1–98 as if fully set forth herein.

100. Upon information and belief, Taro's ANDA Product and its proposed labeling directing use of Taro's ANDA Product infringe one or more claims of the '812 patent either literally or under the doctrine of equivalents.

101. In its Second Notice Letter, Taro does not contest infringement as to claims 1–13, 19, 30–37, 39–53, and 58–66 of the '812 patent.

102. As an example, claim 1 of the '812 patent recites a foamable pharmaceutical vehicle or composition, comprising:

- a. a liquid organic carrier, at a concentration of 10% to 70% by weight of the composition, wherein said organic carrier concurrently comprises:
 - i. at least one hydrophobic organic carrier comprising a triglyceride; and
 - ii. at least one polar solvent comprising dimethyl isosorbide,
- b. a surface-active agent selected from the group consisting of at least one non-ionic surface-active agent, and a mixture of a non-ionic surface-active agent and an

- ionic surface-active agent, wherein the ratio of non-ionic surface-active agent to ionic surface-active agent is greater than 14:1;
- c. water;
 - d. at least one liquefied or compressed gas propellant at a concentration of 3% to 25% by weight of the total composition; and
 - e. a polymeric agent selected from the group consisting of a locust bean gum, sodium caseinate, an egg albumin, a gelatin agar, a carrageenin gum, sodium alginate, a xanthan gum, a quince seed extract, a tragacanth gum, a guar gum, a starch, a chemically modified starch, a cellulose ether, an alkyl cellulose, a hydroxyalkyl cellulose, a hydroxyethyl cellulose, a hydroxypropyl cellulose, a methyl cellulose, a carboxymethyl cellulose, a methylhydroxyethylcellulose, a methylhydroxypropylcellulose, a hydroxypropylmethyl cellulose, a hydroxyethylcarboxymethylcellulose, a carboxymethylhydroxyethylcellulose, a hydroxypropyl guar gum, a soluble starch, a carboxyvinyl polymer, a polyvinylpyrrolidone, a polyvinyl alcohol, a polyacrylic acid polymer, a polymethacrylic acid polymer, a polyvinyl acetate polymer, a polyvinyl chloride polymer, a polyvinylidene chloride polymer, an acrylic acid/ethyl acrylate copolymer, a carboxyvinyl polymer, a silicone dioxide, a poly(acrylic)acid, a poly(methylvinyl ether/maleic anhydride) copolymer, a chitosan, an alginic acid, a hyaluronic acid, a pectin, a karaya gum, a cyclodextrin, a chemically modified cyclodextrin, hydroxypropyl- β -cyclodextrin, a poly(N-isopropylamide), a poloxamer, and mixtures of any two or more thereof; and

wherein the composition is provided in an aerosol container and upon release expands to form a breakable foam that collapses upon application of shear force.

103. Upon information and belief, Taro's ANDA Product and its proposed labeling directing use of Taro's ANDA Product infringe claim 1 of the '812 patent either literally or under the doctrine of equivalents.

104. Taro's submission of ANDA No. 212581 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Taro's ANDA Product prior to the expiration of the '812 patent was an act of infringement of the '812 patent under 35 U.S.C. § 271(e)(2)(A).

105. Upon information and belief, Taro intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Taro's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 212581, *i.e.*, prior to the expiration of the '812 patent.

106. Upon information and belief, Taro has knowledge of the claims of the '812 patent. Notwithstanding this knowledge, Taro has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Taro's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 212581.

107. Upon information and belief, Taro plans and intends to, and will, actively induce infringement of the '812 patent when ANDA No. 212581 is approved, and plans and intends to, and will, do so after approval.

108. Upon information and belief, Taro knows that Taro's ANDA Product is especially made or adapted for use in infringing the '812 patent, and that Taro's ANDA Product is not

suitable for substantial noninfringing use. Upon information and belief, Taro plans and intends to, and will, contribute to infringement of the '812 patent immediately and imminently upon approval of ANDA No. 212581.

109. The foregoing actions by Taro constitute and/or will constitute infringement of the '498 patent, active inducement of infringement of the '812 patent, and contributing to the infringement by others of the '812 patent.

110. Unless Taro is enjoined from infringing the '812 patent, actively inducing infringement of the '498 patent, and contributing to the infringement by others of the '812 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

* * *

111. Taro has proceeded with knowledge of the patents-in-suit and with no reasonable basis to believe that it has not infringed and will not infringe those patents. This is an exceptional case.

* * *

WHEREFORE, the Plaintiffs request the following relief:

- (a) A judgment that Taro has infringed the '076 patent, the '498 patent, the '021 patent, the '554 patent, the '259 patent, the '725 patent, and the '812 patent;
- (b) A judgment ordering that the effective date of any FDA approval for Taro to make, use, offer for sale, sell, market, distribute, or import Taro's ANDA Product, or any product or compound the making, use, offer for sale, sale, marketing, distribution, or importation of which infringes the '076 patent, the '498 patent, the '021 patent, the '554 patent, the '259 patent, the '725 or the '812 patent be not earlier than the expiration date of the '076 patent, the

'498 patent, the '021 patent, the '554 patent, the '259 patent, the '725 patent, and the '812 respectively, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Taro, and all persons acting in concert with Taro, from making, using, offering for sale, selling, marketing, distributing, or importing Taro's ANDA Product, or any product or compound the making, use, offer for sale, sale, marketing, distribution, or importation of which infringes the '076 patent, the '498 patent, the '021 patent, the '554 patent, the '259 patent, the '725 patent, or the '812 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '076 patent, the '498 patent, the '021 patent, the '554 patent, the '259 patent, the '725 patent, or the '812 patent, respectively, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that making, using, offering for sale, selling, marketing, distributing, or importing Taro's ANDA Product, or any product or compound the making, use, offer for sale, sale, marketing, distribution, or importation of which infringes the '076 patent, the '498 patent, the '021 patent, the '554 patent, the '259 patent, the '725 patent, or the '812 patent prior to the expiration date of the '076 patent, the '498 patent, the '021 patent, the '554 patent, the '259 patent, the '725 patent, or the '812 patent, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the '076 patent, the '498 patent, the '021 patent, the '554 patent, the '259 patent, the '725 patent, or the '812 patent;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) An award of the Plaintiffs' costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

WILLIAMS & CONNOLLY LLP

/s/ Samuel Bryant Davidoff

Samuel Bryant Davidoff, #SD9793
650 Fifth Avenue, Suite 1500
New York, NY 10019
(202) 434-5000
sdavidoff@wc.com

Attorneys for Plaintiffs LEO Pharma A/S, LEO Pharma Inc., and Foamix Pharmaceuticals Ltd.

February 4, 2019