

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

VYNE THERAPEUTICS INC., )  
)  
Plaintiff, )  
)  
v. ) C.A. No. \_\_\_\_\_  
)  
PADAGIS ISRAEL PHARMACEUTICALS )  
LTD. (f/k/a PERRIGO ISRAEL )  
PHARMACEUTICALS LTD.), )  
)  
Defendant. )

**COMPLAINT**

Plaintiff VYNE Therapeutics Inc. (“VYNE”), by its attorneys, for its Complaint, alleges as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of defendant’s submission of Abbreviate New Drug Application (“ANDA”) No. 216061 to the U.S. Food and Drug Administration (“FDA”) seeking approval to commercially manufacture, use, offer for sale, sell and/or import a generic version of Amzeeq® prior to the expiration of U.S. Patent Nos. 8,865,139 (“the ’139 patent”); 8,945,516 (“the ’516 patent”); 8,992,896 (“the ’896 patent”); 9,675,700 (“the ’700 patent”); 10,086,080 (“the ’080 patent”); 10,137,200 (“the ’200 patent”); 10,213,512 (“the ’512 patent”); 10,265,404 (“the ’404 patent”); 10,517,882 (“the ’882 patent”); 10,821,187 (“the ’187 patent”); 10,398,641 (“the ’641 patent”); and 10,849,847 (“the ’847 patent”) (collectively the “Amzeeq® Orange Book Patents”).

2. Perrigo Israel Pharmaceuticals, Ltd. (“Perrigo”) notified VYNE by letter dated June 29, 2021 (the “Notice Letter”) that it had submitted to the FDA ANDA No. 216061 (“ANDA”),

seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a topical minocycline foam (“Padagis’s ANDA Product”) prior to the expiration of the Amzeeq® Orange Book Patents.

3. Perrigo notified VYNE by letter dated July 21, 2021 that it had changed its name to Padagis Israel Pharmaceuticals, Ltd. (“Padagis”).

4. On information and belief, Padagis’s ANDA Product is a generic version of VYNE’s Amzeeq® product.

### **PARTIES**

5. Plaintiff VYNE is a corporation organized and existing under the laws of Delaware, having its corporate offices and principal place of business at 520 U.S. Highway 22, Suite 204, Bridgewater, NJ, USA.

6. VYNE is the holder of the NDA No. 212379 for Amzeeq® (4% minocycline topical foam), which has been approved by the FDA for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older.

7. On information and belief, Defendant Padagis is a corporation organized and existing under the laws of Israel, having its principal place of business at 1 Burnstein Zvi, Yeruham, 8050315, Israel. On information and belief, Padagis is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries.

8. On information and belief, Padagis knows and intends that upon approval of Padagis’s ANDA, it will manufacture, market, sell, and distribute Padagis’s ANDA product throughout the United States, including in Delaware.

**JURISDICTION**

9. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. Upon information and belief, Padagis is in the business of, among other things, developing, manufacturing, marketing, importing, and selling generic pharmaceutical products throughout the United States, including in Delaware.

11. Upon information and belief, Padagis, directly or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in Delaware, and, if approved, Padagis's generic version of Amzeeq® foam will be marketed and sold in Delaware.

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

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

14. In addition, this Court has personal jurisdiction over Padagis because Padagis has consented to jurisdiction in this judicial district in previous litigation, and because Padagis has affirmatively availed itself of the courts of this district by filing counterclaims in this district, including in *Sun Pharmaceutical Industries, Inc. et al v. Perrigo Co. et al*, No. 18-703.

15. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b), (c) and 1400(b).

## **BACKGROUND**

16. Amzeeq® foam (active ingredient 4% minocycline) is a topical prescription medicine indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older.

17. The '139 patent entitled "Topical Tetracycline Compositions" (Exhibit A hereto) was duly and legally issued on October 21, 2014. Amzeeq® foam and the use thereof are covered by one or more claims of the '139 patent, which has been listed in connection with Amzeeq® foam in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book."

18. The '516 patent, entitled "Surfactant-Free Water-Free Foamable Compositions, Breakable Foams and Gels and Their Uses" (Exhibit B hereto) was duly and legally issued on February 3, 2015. Amzeeq® foam and the use thereof are covered by one or more claims of the '516 patent, which has been listed in connection with Amzeeq® foam in the Orange Book.

19. The '896 patent, entitled "Topical Tetracycline Compositions" (Exhibit C hereto) was duly and legally issued on March 31, 2015. Amzeeq® foam and the use thereof are covered by one or more claims of the '896 patent, which has been listed in connection with Amzeeq® foam in the Orange Book.

20. The '700 patent, entitled "Topical Tetracycline Compositions" (Exhibit D hereto) was duly and legally issued on June 13, 2017. Amzeeq® foam and the use thereof are covered by one or more claims of the '700 patent, which has been listed in connection with Amzeeq® foam in the Orange Book.

21. The '080 patent, entitled "Topical Tetracycline Compositions" (Exhibit E hereto) was duly and legally issued on October 2, 2018. Amzeeq® foam and the use thereof are covered

by one or more claims of the '080 patent, which has been listed in connection with Amzeeq® foam in the Orange Book.

22. The '200 patent, entitled “Surfactant-Free Water-Free Foamable Compositions, Breakable Foams and Gels and Their Uses” (Exhibit F hereto) was duly and legally issued on November 27, 2018. Amzeeq® foam and the use thereof are covered by one or more claims of the '200 patent, which has been listed in connection with Amzeeq® foam in the Orange Book.

23. The '512 patent, entitled “Topical Tetracycline Compositions” (Exhibit G hereto) was duly and legally issued on February 26, 2019. Amzeeq® foam and the use thereof are covered by one or more claims of the '512 patent, which has been listed in connection with Amzeeq® foam in the Orange Book.

24. The '404 patent, entitled “Compositions, Gels and Foams with Rheology Modulators and Uses Thereof” (Exhibit H hereto) was duly and legally issued on April 23, 2019. Amzeeq® foam and the use thereof are covered by one or more claims of the '404 patent, which has been listed in connection with Amzeeq® foam in the Orange Book.

25. The '882 patent, entitled “Method for Healing of an Infected Acne Lesion Without Scarring” (Exhibit I hereto) was duly and legally issued on December 31, 2019. Amzeeq® foam and the use thereof are covered by one or more claims of the '882 patent, which has been listed in connection with Amzeeq® foam in the Orange Book.

26. The '187 patent, entitled “Compositions, Gels and Foams with Rheology Modulators and Uses Thereof” (Exhibit J hereto) was duly and legally issued on November 3, 2020. Amzeeq® foam and the use thereof are covered by one or more claims of the '187 patent, which has been listed in connection with Amzeeq® foam in the Orange Book.

27. The '641 patent, entitled "Compositions and Methods for Treating Rosacea and Acne" (Exhibit K hereto) was duly and legally issued on September 3, 2019. Amzeeq® foam and the use thereof are covered by one or more claims of the '641 patent, which has been listed in connection with Amzeeq® foam in the Orange Book.

28. The '847 patent, entitled "Compositions and Methods for Treating Rosacea and Acne" (Exhibit L hereto) was duly and legally issued on December 1, 2020. Amzeeq® foam and the use thereof are covered by one or more claims of the '847 patent, which has been listed in connection with Amzeeq® foam in the Orange Book.

29. VYNE has all right, title, and interest in the Orange Book Patents, including the right to sue for infringement of those patents.

30. VYNE is the holder of New Drug Application No. 212379 for Amzeeq® foam, which has been approved by the FDA for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older.

31. On or about June 30, 2021, VYNE received the Notice Letter stating that Perrigo (now Padagis) has submitted to the FDA ANDA No. 216061 for a 4% topical minocycline foam. On information and belief, Padagis's ANDA Product is a drug product that is a generic version of Amzeeq® foam.

32. The purpose of Padagis's submission of ANDA No. 216061 was to obtain approval 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 Padagis's ANDA Product prior to the expiration of the Amzeeq® foam Orange Book Patents.

33. In the Notice Letter, Padagis indicated that, in connection with its ANDA No. 216061, Padagis had filed Paragraph IV Certifications with respect to each of the Amzeeq® Orange Book Patents.

34. In the Notice Letter, Padagis asserted that each of the Orange Book Patents was invalid. Padagis further asserted that it did not infringe certain method of treatment claims in the Orange Book Patents.

35. Padagis made no assertion in the Notice Letter that its ANDA Product does not infringe the composition claims of the Orange Book Patents, assuming those patent claims are valid.

36. This action is being commenced before the expiration of forty-five days from the receipts of the Notice Letter.

**COUNT I – INFRINGEMENT OF U.S. PATENT NO. 8,865,139**

37. Plaintiff fully incorporate each of the preceding paragraphs 1-36 as if fully set forth herein.

38. Upon information and belief, Padagis's ANDA Product infringes one or more claims of the '139 patent either literally or under the doctrine of equivalents.

39. As a non-limiting example, claim 1 of the '139 patent recites a composition comprising:

a carrier comprising:

- a) about 60% to 99% by weight of the composition of at least one hydrophobic oil; and
- b) at least one viscosity-modifying agent that is a combination comprising
  - (i) at least one fatty alcohol and at least one wax; (ii) at least one fatty acid

and at least one wax; or (iii) at least one fatty alcohol, at least one fatty acid,  
and at least one wax,

wherein the wax is selected from the group consisting of a plant wax, an animal wax, a petroleum derived wax, and a vegetable wax; or wherein the wax is selected from the group consisting of an albacer wax, an atlasene wax, a cardis wax, a ceramid, an alkyl-substituted aromatic compound, a naphthene-substituted aromatic compound, a beeswax, a BASF wax, a carnauba wax, a chinese wax, a cotton wax, a bayberry wax, a carnauba wax, a castor wax, a cuban palm wax, a duroxon wax, an esparto wax, a fat wax, a flax wax, a fischer-tropsch wax, a fir wax, a flexo wax, a flower wax, glyco waxes, a japan wax, a jojoba oil, a lanolin wax, a palm wax, a rice bran wax, a rice-oil wax, a shellac wax, a soy wax, an ucuhuba wax, a hydrogenated oil, a hydrogenated castor oil, a hydrogenated cottonseed oil, a hydrogenated jojoba oil, a mink wax, a mixture of Saturated n- and isoalkanes, a montan wax, a naphthene, an ouricury wax, an oxazoline wax, an ozokerite, a paraffin wax, a paraffin 58-62°C. wax, paraffin 51-53°C. wax, paraffin 42-44°C. wax, a polyethylene wax, a PEG-6 beeswax, a polymekon wax, a retamo wax, a rezo wax, a sandy wax, a spent grain wax, a stearyl dimethicone, a sugarcane wax, a synthetic mineral wax, and mixtures and any two or more thereof;

the carrier being otherwise free of or containing less than 0.1% by weight of a surfactant;

a tetracycline antibiotic, at least part of which is suspended in the composition; and

a liquefied or compressed gas propellant;

wherein the composition is waterless; and



wherein when packaged in an aerosol container and pressurized with a liquefied or compressed gas propellant, the composition affords upon release from the container a foam that breaks upon application of shear force.

40. Upon information and belief, Padagis's ANDA Product infringes claim 1 of the '139 patent literally or under the doctrine of equivalents. The Notice Letter does not contain any factual basis to assert noninfringement of claim 1 of the '139 patent.

41. Padagis's submission of ANDA 216061 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's ANDA Product prior to the expiration of the '139 patent was an act of infringement of the '139 patent under 35 U.S.C. § 271(e)(2)(A).

42. Upon information and belief, Padagis intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 216061, i.e., prior to the expiration of the '139 patent.

43. Upon information and belief, Padagis has knowledge of the claims of the '139 patent. Notwithstanding this knowledge, Padagis has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 216061.

44. Upon information and belief, Padagis plans and intends to, and will, actively induce infringement of the '139 patent when ANDA No. 216061 is approved, and plans and intends to, and will, do so after approval. Padagis will do so with knowledge of the '139 patent and with specific intent to induce infringement of that patent.

45. Upon information and belief, Padagis knows that Padagis's ANDA Product is especially made or adapted for use in infringing the '139 patent, and that Padagis's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Padagis plans and intends to, and will, contribute to infringement of the '139 patent immediately and imminently upon approval of ANDA No. 216061.

46. The foregoing actions by Padagis constitute and/or will constitute infringement of the '139 patent, active inducement of infringement of the '139 patent, and contributing to the infringement by others of the '139 patent.

47. Unless Padagis is enjoined from infringing the '139 patent, actively inducing infringement of the '139 patent, and contributing to the infringement by others of the '139 patent, Plaintiff will suffer irreparable injury. Plaintiff have no adequate remedy at law.

**COUNT II – DECLARATORY JUDGMENT  
OF INFRINGEMENT OF THE '139 PATENT**

48. VYNE incorporates each of the preceding paragraphs 1-47 as if fully set forth herein.

49. The Court may declare the rights of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between VYNE on the one hand and Padagis on the other regarding Padagis's infringement, active inducement of infringement, and contribution to the infringement by others of the '139 patent.

50. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Padagis's ANDA Product with its proposed labeling, or any other Padagis drug product that is covered by or the use of which is covered by the '139 patent will infringe, induce the infringement of, and contribute to the infringement by others of the '139 patent and that the claims of the '139 patent are valid.

**COUNT III – INFRINGEMENT OF U.S. PATENT NO. 8,945,516**

51. Plaintiff fully incorporate each of the preceding paragraphs 1-50 as if fully set forth herein.

52. Upon information and belief, Padagis's ANDA Product infringes one or more claims of the '516 patent either literally or under the doctrine of equivalents.

53. As a non-limiting example, claim 1 of the '516 patent recites a surfactant free flowable foamable composition comprising:

a carrier comprising:

a) about 60% to about 95% by weight of the carrier of a hydrophobic solvent, wherein the hydrophobic solvent is an oil; and

b) an oleaginous foamer complex comprising:

(1) about 0.1% to about 20% by weight of the carrier of at least one fatty alcohol, wherein the fatty alcohol has a carbon chain length of 14 to 22 carbons; and

(2) about 0.1% to about 20% by weight of the carrier of at least one fatty acid, at least one wax, at least one shea butter, or mixtures of two or more thereof, wherein the fatty acid has a carbon chain length of 12 to 28 carbons, and the wax is selected from the group consisting of a beeswax, a hydrogenated castor oil, a paraffin wax, a wax that is solid at room temperature, and mixtures of two or more thereof, and

a liquefied or compressed gas propellant;

wherein the composition comprises 15% or less than 15% of petrolatum by weight of the carrier;

wherein the composition is essentially waterless;

wherein the composition is free of polymeric agent; and

wherein the ratio of carrier to propellant is from about 100:3 to about 100:30; and wherein upon dispensing, the flowable foamable composition forms a breakable foam that breaks easily upon application of shear force.

54. Upon information and belief, Padagis's ANDA Product infringes claim 1 of the '516 patent literally or under the doctrine of equivalents. The Notice Letter does not contain any factual basis to assert noninfringement of claim 1 of the '516 patent.

55. Padagis's submission of ANDA 216061 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's ANDA Product prior to the expiration of the '516 patent was an act of infringement of the '516 patent under 35 U.S.C. § 271(e)(2)(A).

56. Upon information and belief, Padagis intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 216061, i.e., prior to the expiration of the '516 patent.

57. Upon information and belief, Padagis has knowledge of the claims of the '516 patent. Notwithstanding this knowledge, Padagis has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 216061.

58. Upon information and belief, Padagis plans and intends to, and will, actively induce infringement of the '516 patent when ANDA No. 216061 is approved, and plans and intends to, and will, do so after approval. Padagis will do so with knowledge of the '516 patent and with specific intent to induce infringement of that patent.

59. Upon information and belief, Padagis knows that Padagis's ANDA Product is especially made or adapted for use in infringing the '516 patent, and that Padagis's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Padagis plans and intends to, and will, contribute to infringement of the '516 patent immediately and imminently upon approval of ANDA No. 216061.

60. The foregoing actions by Padagis constitute and/or will constitute infringement of the '516 patent, active inducement of infringement of the '516 patent, and contributing to the infringement by others of the '516 patent.

61. Unless Padagis is enjoined from infringing the '516 patent, actively inducing infringement of the '516 patent, and contributing to the infringement by others of the '516 patent, Plaintiff will suffer irreparable injury. Plaintiff have no adequate remedy at law.

**COUNT IV – DECLARATORY JUDGMENT  
OF INFRINGEMENT OF THE '516 PATENT**

62. VYNE incorporates each of the preceding paragraphs 1-61 as if fully set forth herein.

63. The Court may declare the rights of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between VYNE on the one hand and Padagis on the other regarding Padagis's infringement, active inducement of infringement, and contribution to the infringement by others of the '516 patent.

64. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Padagis's ANDA Product with its proposed labeling, or any other Padagis drug product that is covered by or the use of which is covered by the '516 patent will infringe, induce the infringement of, and contribute to the infringement by others of the '516 patent and that the claims of the '516 patent are valid.

**COUNT V – INFRINGEMENT OF U.S. PATENT NO. 8,992,896**

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

66. Upon information and belief, Padagis's ANDA Product infringes one or more claims of the '896 patent either literally or under the doctrine of equivalents.

67. As a non-limiting example, claim 1 of the '896 patent recites a composition comprising:

a carrier comprising:

a) about 60% to 99% by weight of the composition of at least one hydrophobic oil; and

b) at least one viscosity-modifying agent that is a combination comprising (i) at least one fatty alcohol and at least one wax; (ii) at least one fatty acid and at least one wax; or (iii) at least one fatty alcohol, at least one fatty acid, and at least one wax,

wherein the composition does not contain one or more of a minocycline incompatible substance selected from the group consisting of dimethyl sulfoxide (DMSO), dimethylformamide (DMF), acetonitrile, acetone, methyl ethyl ketone, 1,4-dioxane, tetrahydrofuran (THF), N-methylpyrrolidone, pyridine, piperidine, dimethyl formamide, N-methyl-2-pyrrolidone and 1-methyl-2-pyrrolidinone), azone (1-dodecylazacycloheptan-2-one), dimethyl isosorbide, glycerin, ethanol, propylene glycol, butylene glycol, PEG 200, hexylene glycol, PEG 400, diethylene glycol monoethyl ether, pomegranate seed oil, and isostearic acid, and ethocel;

the carrier being otherwise free of or containing less than 0.1% by weight of a surfactant;

a tetracycline antibiotic; and

wherein the composition is waterless; and

wherein when packaged in an aerosol container and pressurized with a propellant, the composition affords upon release from the container a foam that breaks upon application of shear force.

68. Upon information and belief, Padagis's ANDA Product infringes claim 1 of the '896 patent literally or under the doctrine of equivalents. The Notice Letter does not contain any factual basis to assert noninfringement of claim 1 of the '896 patent.

69. Padagis's submission of ANDA 216061 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's ANDA Product prior to the expiration of the '896 patent was an act of infringement of the '896 patent under 35 U.S.C. § 271(e)(2)(A).

70. Upon information and belief, Padagis intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 216061, i.e., prior to the expiration of the '896 patent.

71. Upon information and belief, Padagis has knowledge of the claims of the '896 patent. Notwithstanding this knowledge, Padagis has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 216061.

72. Upon information and belief, Padagis plans and intends to, and will, actively induce infringement of the '896 patent when ANDA No. 216061 is approved, and plans and intends to, and will, do so after approval. Padagis will do so with knowledge of the '896 patent and with specific intent to induce infringement of that patent.

73. Upon information and belief, Padagis knows that Padagis's ANDA Product is especially made or adapted for use in infringing the '896 patent, and that Padagis's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Padagis plans and intends to, and will, contribute to infringement of the '896 patent immediately and imminently upon approval of ANDA No. 216061.

74. The foregoing actions by Padagis constitute and/or will constitute infringement of the '896 patent, active inducement of infringement of the '896 patent, and contributing to the infringement by others of the '896 patent.

75. Unless Padagis is enjoined from infringing the '896 patent, actively inducing infringement of the '896 patent, and contributing to the infringement by others of the '896 patent, Plaintiff will suffer irreparable injury. Plaintiff have no adequate remedy at law.

**COUNT VI – DECLARATORY JUDGMENT  
OF INFRINGEMENT OF THE '896 PATENT**

76. VYNE incorporates each of the preceding paragraphs 1-75 as if fully set forth herein.

77. The Court may declare the rights of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between VYNE on the one hand and Padagis on the other regarding Padagis's infringement, active inducement of infringement, and contribution to the infringement by others of the '896 patent.

78. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Padagis's ANDA Product with its proposed labeling, or any other Padagis drug product that is covered by or the use of which is covered by the '896 patent will infringe, induce the infringement of, and contribute to the infringement by others of the '896 patent and that the claims of the '896 patent are valid.



**COUNT VII – INFRINGEMENT OF U.S. PATENT NO. 9,675,700**

79. Plaintiff fully incorporate each of the preceding paragraphs 1-78 as if fully set forth herein.

80. Upon information and belief, Padagis's ANDA Product infringes one or more claims of the '700 patent either literally or under the doctrine of equivalents.

81. As a non-limiting example, claim 1 of the '700 patent recites a waterless composition comprising:

a tetracycline antibiotic and a carrier, the carrier comprising:

- a) at least one hydrophobic oil; and
- b) an agent comprising (i) at least one fatty alcohol and at least one wax; (ii) at least one fatty acid and at least one wax, (iii) at least one fatty alcohol, at least one fatty acid, and at least one wax; (iv) a wax comprising a hydrogenated oil; or (v) a combination of two or more waxes;

wherein the composition does not contain one or more minocycline incompatible substance selected from the group consisting of dimethyl sulfoxide (DMSO), dimethylformamide (DMF), acetonitrile, acetone, methyl ethyl ketone, 1,4-dioxane, tetrahydrofuran (THF), N-methylpyrrolidone, pyridine, piperidine, N-methyl 2-pyrrolidone and 1-methyl-2-pyrrolidinone), azone (1-dodecylazacycloheptan-2-one), dimethyl isosorbide, glycerin, ethanol, propylene glycol, butylene glycol, PEG 200, hexylene glycol, PEG 400, diethylene glycol monoethyl ether, pomegranate seed oil, isostearic acid, and ethocel;

and wherein the composition does not contain a polyol and/or polyethylene glycol.

82. Upon information and belief, Padagis's ANDA Product infringes claim 1 of the '700 patent literally or under the doctrine of equivalents. The Notice Letter does not contain any factual basis to assert noninfringement of claim 1 of the '700 patent.

83. Padagis's submission of ANDA 216061 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's ANDA Product prior to the expiration of the '700 patent was an act of infringement of the '700 patent under 35 U.S.C. § 271(e)(2)(A).

84. Upon information and belief, Padagis intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 216061, i.e., prior to the expiration of the '700 patent.

85. Upon information and belief, Padagis has knowledge of the claims of the '700 patent. Notwithstanding this knowledge, Padagis has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 216061.

86. Upon information and belief, Padagis plans and intends to, and will, actively induce infringement of the '700 patent when ANDA No. 216061 is approved, and plans and intends to, and will, do so after approval. Padagis will do so with knowledge of the '700 patent and with specific intent to induce infringement of that patent.

87. Upon information and belief, Padagis knows that Padagis's ANDA Product is especially made or adapted for use in infringing the '700 patent, and that Padagis's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Padagis plans and

intends to, and will, contribute to infringement of the '700 patent immediately and imminently upon approval of ANDA No. 216061.

88. The foregoing actions by Padagis constitute and/or will constitute infringement of the '700 patent, active inducement of infringement of the '700 patent, and contributing to the infringement by others of the '700 patent.

89. Unless Padagis is enjoined from infringing the '700 patent, actively inducing infringement of the '700 patent, and contributing to the infringement by others of the '700 patent, Plaintiff will suffer irreparable injury. Plaintiff have no adequate remedy at law.

**COUNT VIII – DECLARATORY JUDGMENT  
OF INFRINGEMENT OF THE '700 PATENT**

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

91. The Court may declare the rights of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between VYNE on the one hand and Padagis on the other regarding Padagis's infringement, active inducement of infringement, and contribution to the infringement by others of the '700 patent.

92. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Padagis's ANDA Product with its proposed labeling, or any other Padagis drug product that is covered by or the use of which is covered by the '700 patent will infringe, induce the infringement of, and contribute to the infringement by others of the '700 patent and that the claims of the '700 patent are valid.

**COUNT IX – INFRINGEMENT OF U.S. PATENT NO. 10,086,080**

93. Plaintiff fully incorporate each of the preceding paragraphs 1-92 as if fully set forth herein.

94. Upon information and belief, Padagis's ANDA Product infringes one or more claims of the '080 patent either literally or under the doctrine of equivalents.

95. As a non-limiting example, claim 1 of the '080 patent recites a method of treating acne vulgaris, comprising administering:

a waterless foam composition comprising

a minocycline and a foamable carrier, the carrier comprising:

- a) at least one hydrophobic oil; and
- b) an agent comprising (i) at least one fatty alcohol and at least one wax; (ii) at least one fatty acid and at least one wax; (iii) at least one fatty alcohol, at least one fatty acid, and at least one wax; (iv) a wax comprising a hydrogenated oil; or (v) a combination of two or more waxes;

wherein the composition does not contain one or more minocycline incompatible substance selected from the group consisting of dimethyl sulfoxide (DMSO), dimethylformamide (DMF), acetonitrile, acetone, methyl ethyl ketone, 1,4-dioxane, tetrahydrofuran (THF), N-methylpyrrolidone, pyridine, piperidine, N-methyl 2-pyrrolidone and 1-methyl-2-pyrrolidinone), azone (1-dodecylazacycloheptan-2-one), dimethyl isosorbide, glycerin, ethanol, propylene glycol, butylene glycol, PEG 200, hexylene glycol, PEG 400, diethylene glycol monoethyl ether, pomegranate seed oil, isostearic acid, and ethocel;

wherein the composition does not contain a surfactant; and

wherein the composition does not contain a polyol.

96. Upon information and belief, the use of Padagis's ANDA Product infringes claim 1 of the '080 patent literally or under the doctrine of equivalents. The Notice Letter does not contain any factual basis to assert noninfringement of claim 1 of the '080 patent.

97. Padagis's submission of ANDA 216061 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's ANDA Product prior to the expiration of the '080 patent was an act of infringement of the '080 patent under 35 U.S.C. § 271(e)(2)(A).

98. Upon information and belief, Padagis intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 216061, i.e., prior to the expiration of the '080 patent.

99. Upon information and belief, Padagis has knowledge of the claims of the '080 patent. Notwithstanding this knowledge, Padagis has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 216061.

100. Upon information and belief, Padagis plans and intends to, and will, actively induce infringement of the '080 patent when ANDA No. 216061 is approved, and plans and intends to, and will, do so after approval. Padagis will do so with knowledge of the '080 patent and with specific intent to induce infringement of that patent.

101. Upon information and belief, Padagis knows that Padagis's ANDA Product is especially made or adapted for use in infringing the '080 patent, and that Padagis's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Padagis plans and intends to, and will, contribute to infringement of the '080 patent immediately and imminently upon approval of ANDA No. 216061.

102. The foregoing actions by Padagis constitute and/or will constitute infringement of the '080 patent, active inducement of infringement of the '080 patent, and contributing to the infringement by others of the '080 patent.

103. Unless Padagis is enjoined from infringing the '080 patent, actively inducing infringement of the '080 patent, and contributing to the infringement by others of the '080 patent, Plaintiff will suffer irreparable injury. Plaintiff have no adequate remedy at law.

**COUNT X – DECLARATORY JUDGMENT  
OF INFRINGEMENT OF THE '080 PATENT**

104. VYNE incorporates each of the preceding paragraphs 1-103 as if fully set forth herein.

105. The Court may declare the rights of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between VYNE on the one hand and Padagis on the other regarding Padagis's infringement, active inducement of infringement, and contribution to the infringement by others of the '080 patent.

106. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Padagis's ANDA Product with its proposed labeling, or any other Padagis drug product that is covered by or the use of which is covered by the '080 patent will infringe, induce the infringement of, and contribute to the infringement by others of the '080 patent and that the claims of the '080 patent are valid.

**COUNT XI – INFRINGEMENT OF U.S. PATENT NO. 10,137,200**

107. Plaintiff fully incorporate each of the preceding paragraphs 1-106 as if fully set forth herein.

108. Upon information and belief, Padagis's ANDA Product infringes one or more claims of the '200 patent either literally or under the doctrine of equivalents.

109. As a non-limiting example, claim 1 of the '200 patent recites a method of treating acne vulgaris, comprising administering a surfactant free foam composition dispensed from a container, wherein the container comprises:

i) A carrier comprising:

a) about 60% to 95% by weight of the carrier of a hydrophobic solvent, wherein the hydrophobic solvent is an oil;

b) about 0.1% to about 20% by weight of the carrier of at least one fatty alcohol,

wherein the fatty alcohol has a carbon chain length of 14 to 22 carbons;

c) about 0.1% to about 20% by weight of the carrier of at least one fatty acid, at least one wax, at least one shea butter, or mixtures of two or more thereof, wherein the fatty acid has a carbon chain length of 12 to 28 carbons, and the wax is selected from the group consisting of a beeswax, a hydrogenated castor oil, a paraffin wax, a wax that is solid at room temperature, and a mixture of any two or more thereof; and

d) a minocycline antibiotic; and

ii) a liquefied or compressed gas propellant;

wherein the composition comprises 15% or less of petrolatum by weight of the carrier;

wherein the composition is essentially waterless;

wherein the composition is free of polymeric agent;

and wherein, upon dispensing, the composition forms a foam.

110. Upon information and belief, the use of Padagis's ANDA Product infringes claim 1 of the '200 patent literally or under the doctrine of equivalents. The Notice Letter does not contain any factual basis to assert noninfringement of claim 1 of the '200 patent.

111. Padagis's submission of ANDA 216061 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's ANDA Product prior to the expiration of the '200 patent was an act of infringement of the '200 patent under 35 U.S.C. § 271(e)(2)(A).

112. Upon information and belief, Padagis intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 216061, i.e., prior to the expiration of the '200 patent.

113. Upon information and belief, Padagis has knowledge of the claims of the '200 patent. Notwithstanding this knowledge, Padagis has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 216061.

114. Upon information and belief, Padagis plans and intends to, and will, actively induce infringement of the '200 patent when ANDA No. 216061 is approved, and plans and intends to, and will, do so after approval. Padagis will do so with knowledge of the '200 patent and with specific intent to induce infringement of that patent.

115. Upon information and belief, Padagis knows that Padagis's ANDA Product is especially made or adapted for use in infringing the '200 patent, and that Padagis's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Padagis plans and



intends to, and will, contribute to infringement of the '200 patent immediately and imminently upon approval of ANDA No. 216061.

116. The foregoing actions by Padagis constitute and/or will constitute infringement of the '200 patent, active inducement of infringement of the '200 patent, and contributing to the infringement by others of the '200 patent.

117. Unless Padagis is enjoined from infringing the '200 patent, actively inducing infringement of the '200 patent, and contributing to the infringement by others of the '200 patent, Plaintiff will suffer irreparable injury. Plaintiff have no adequate remedy at law.

**COUNT XII – DECLARATORY JUDGMENT  
OF INFRINGEMENT OF THE '200 PATENT**

118. VYNE incorporates each of the preceding paragraphs 1-117 as if fully set forth herein.

119. The Court may declare the rights of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between VYNE on the one hand and Padagis on the other regarding Padagis's infringement, active inducement of infringement, and contribution to the infringement by others of the '200 patent.

120. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Padagis's ANDA Product with its proposed labeling, or any other Padagis drug product that is covered by or the use of which is covered by the '200 patent will infringe, induce the infringement of, and contribute to the infringement by others of the '200 patent and that the claims of the '200 patent are valid.

**COUNT XIII – INFRINGEMENT OF U.S. PATENT NO. 10,213,512**

121. Plaintiff fully incorporate each of the preceding paragraphs 1-120 as if fully set forth herein.

122. Upon information and belief, Padagis's ANDA Product infringes one or more claims of the '512 patent either literally or under the doctrine of equivalents.

123. As a non-limiting example, claim 1 of the '512 patent recites a foamable, waterless, surfactant-free composition comprising a carrier and a liquefied or compressed gas propellant, the carrier comprising:

- a) a tetracycline antibiotic
- b) a combination of two or more hydrophobic oils, wherein at least one of the hydrophobic oils is a light mineral oil and the other hydrophobic oil comprises a heavy mineral oil, soybean oil, and/or coconut oil;
- c) a combination of two or more fatty alcohols, wherein at least one of the fatty alcohols is stearyl alcohol;
- d) optionally stearic acid; and
- e) wherein the carrier comprises at least one wax;

wherein the hydrophobic oils are present at between about 70% and 95% by weight of the carrier;

wherein ratio of the fatty alcohols to stearic acid, if present, is between 4:1 and 1:4;

wherein the fatty alcohols and the wax are present at a ratio between about 4:1 and 3:2;

wherein the ratio of the carrier to the propellant is between about 100:1 and about 100:25; wherein upon release from an aerosol container, the composition forms a foam.

124. Upon information and belief, Padagis's ANDA Product infringes claim 1 of the '512 patent literally or under the doctrine of equivalents. The Notice Letter does not contain any factual basis to assert noninfringement of claim 1 of the '512 patent.

125. Padagis's submission of ANDA 216061 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's ANDA Product prior to the expiration of the '512 patent was an act of infringement of the '512 patent under 35 U.S.C. § 271(e)(2)(A).

126. Upon information and belief, Padagis intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 216061, i.e., prior to the expiration of the '512 patent.

127. Upon information and belief, Padagis has knowledge of the claims of the '512 patent. Notwithstanding this knowledge, Padagis has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 216061.

128. Upon information and belief, Padagis plans and intends to, and will, actively induce infringement of the '512 patent when ANDA No. 216061 is approved, and plans and intends to, and will, do so after approval. Padagis will do so with knowledge of the '512 patent and with specific intent to induce infringement of that patent.

129. Upon information and belief, Padagis knows that Padagis's ANDA Product is especially made or adapted for use in infringing the '512 patent, and that Padagis's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Padagis plans and intends to, and will, contribute to infringement of the '512 patent immediately and imminently upon approval of ANDA No. 216061.

130. The foregoing actions by Padagis constitute and/or will constitute infringement of the '512 patent, active inducement of infringement of the '512 patent, and contributing to the infringement by others of the '512 patent.

131. Unless Padagis is enjoined from infringing the '512 patent, actively inducing infringement of the '512 patent, and contributing to the infringement by others of the '512 patent, Plaintiff will suffer irreparable injury. Plaintiff have no adequate remedy at law.

**COUNT XIV – DECLARATORY JUDGMENT  
OF INFRINGEMENT OF THE '512 PATENT**

132. VYNE incorporates each of the preceding paragraphs 1-131 as if fully set forth herein.

133. The Court may declare the rights of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between VYNE on the one hand and Padagis on the other regarding Padagis's infringement, active inducement of infringement, and contribution to the infringement by others of the '512 patent.

134. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Padagis's ANDA Product with its proposed labeling, or any other Padagis drug product that is covered by or the use of which is covered by the '512 patent will infringe, induce the infringement of, and contribute to the infringement by others of the '512 patent and that the claims of the '512 patent are valid.

**COUNT XV – INFRINGEMENT OF U.S. PATENT NO. 10,265,404**

135. Plaintiff fully incorporate each of the preceding paragraphs 1-134 as if fully set forth herein.

136. Upon information and belief, Padagis's ANDA Product infringes one or more claims of the '404 patent either literally or under the doctrine of equivalents.

137. As a non-limiting example, claim 1 of the '404 patent recites an oleaginous foam composition comprising:

a) a combination of at least one fatty alcohol and at least one wax; or a combination of at least one fatty alcohol, at least one fatty acid, and at least one wax;

b) at least one hydrophobic solvent; and

c) a minocycline at a concentration between about 1% and about 4% by weight of the composition;

wherein the composition is free of surfactant;

wherein the composition is essentially waterless;

wherein the ratio of (1) fatty alcohol to wax or (2) fatty alcohol and fatty acid to wax is between about 1:3 and 3:1; and

wherein the wax comprises a mixture of beeswax and hydrogenated castor oil.

138. Upon information and belief, Padagis's ANDA Product infringes claim 1 of the '404 patent literally or under the doctrine of equivalents. The Notice Letter does not contain any factual basis to assert noninfringement of claim 1 of the '404 patent.

139. Padagis's submission of ANDA 216061 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's ANDA Product prior to the expiration of the '404 patent was an act of infringement of the '404 patent under 35 U.S.C. § 271(e)(2)(A).

140. Upon information and belief, Padagis intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 216061, i.e., prior to the expiration of the '404 patent.

141. Upon information and belief, Padagis has knowledge of the claims of the '404 patent. Notwithstanding this knowledge, Padagis has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 216061.

142. Upon information and belief, Padagis plans and intends to, and will, actively induce infringement of the '404 patent when ANDA No. 216061 is approved, and plans and intends to, and will, do so after approval. Padagis will do so with knowledge of the '404 patent and with specific intent to induce infringement of that patent.

143. Upon information and belief, Padagis knows that Padagis's ANDA Product is especially made or adapted for use in infringing the '404 patent, and that Padagis's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Padagis plans and intends to, and will, contribute to infringement of the '404 patent immediately and imminently upon approval of ANDA No. 216061.

144. The foregoing actions by Padagis constitute and/or will constitute infringement of the '404 patent, active inducement of infringement of the '404 patent, and contributing to the infringement by others of the '404 patent.

145. 'Unless Padagis is enjoined from infringing the '404 patent, actively inducing infringement of the '404 patent, and contributing to the infringement by others of the '404 patent, Plaintiff will suffer irreparable injury. Plaintiff have no adequate remedy at law.

**COUNT XVI – DECLARATORY JUDGMENT  
OF INFRINGEMENT OF THE '404 PATENT**

146. VYNE incorporates each of the preceding paragraphs 1-145 as if fully set forth herein.

147. The Court may declare the rights of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between VYNE on the one hand and Padagis on the other regarding Padagis's infringement, active inducement of infringement, and contribution to the infringement by others of the '404 patent.

148. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Padagis's ANDA Product with its proposed labeling, or any other Padagis drug product that is covered by or the use of which is covered by the '404 patent will infringe, induce the infringement of, and contribute to the infringement by others of the '404 patent and that the claims of the '404 patent are valid.

**COUNT XVII – INFRINGEMENT OF U.S. PATENT NO. 10,517,882**

149. Plaintiff fully incorporate each of the preceding paragraphs 1-148 as if fully set forth herein.

150. Upon information and belief, Padagis's ANDA Product infringes one or more claims of the '882 patent either literally or under the doctrine of equivalents.

151. As a non-limiting example, claim 1 of the '882 patent recites a method of healing an infected acne lesion without scarring, comprising topically administering at least once daily an effective amount of a minocycline antibiotic foam to an infected acne lesion, wherein the minocycline antibiotic foam is produced from a foamable composition upon addition of a liquefied or compressed gas propellant, the foamable composition comprising:

- (a) 60% to 90% by weight of one or more hydrophobic oils selected from the group consisting of a mineral oil, a soybean oil, a coconut oil, cyclomethicone, and a mixture of two or more thereof;

- (b) a wax selected from the group consisting of a beeswax, a hydrogenated castor oil, and a mixture thereof;
- (c) at least one solid fatty alcohol having a carbon chain length of 14 to 22 carbons
- (d) at least one solid fatty acid having a carbon chain length of 12 to 28 carbons;
- and
- (e) 0.2% to 10% by weight of a minocycline; and

wherein the foamable composition does not comprise a surfactant.

152. Upon information and belief, the use of Padagis's ANDA Product infringes claim 1 of the '882 patent literally or under the doctrine of equivalents. The Notice Letter does not contain any factual basis to assert noninfringement of claim 1 of the '882 patent.

153. Padagis's submission of ANDA 216061 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's ANDA Product prior to the expiration of the '882 patent was an act of infringement of the '882 patent under 35 U.S.C. § 271(e)(2)(A).

154. Upon information and belief, Padagis intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 216061, i.e., prior to the expiration of the '882 patent.

155. Upon information and belief, Padagis has knowledge of the claims of the '882 patent. Notwithstanding this knowledge, Padagis has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 216061.



156. Upon information and belief, Padagis plans and intends to, and will, actively induce infringement of the '882 patent when ANDA No. 216061 is approved, and plans and intends to, and will, do so after approval. Padagis will do so with knowledge of the '882 patent and with specific intent to induce infringement of that patent.

157. Upon information and belief, Padagis knows that Padagis's ANDA Product is especially made or adapted for use in infringing the '882 patent, and that Padagis's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Padagis plans and intends to, and will, contribute to infringement of the '882 patent immediately and imminently upon approval of ANDA No. 216061.

158. The foregoing actions by Padagis constitute and/or will constitute infringement of the '882 patent, active inducement of infringement of the '882 patent, and contributing to the infringement by others of the '882 patent.

159. Unless Padagis is enjoined from infringing the '882 patent, actively inducing infringement of the '882 patent, and contributing to the infringement by others of the '882 patent, Plaintiff will suffer irreparable injury. Plaintiff have no adequate remedy at law.

**COUNT XVIII – DECLARATORY JUDGMENT  
OF INFRINGEMENT OF THE '882 PATENT**

160. VYNE incorporates each of the preceding paragraphs 1-159 as if fully set forth herein.

161. The Court may declare the rights of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between VYNE on the one hand and Padagis on the other regarding Padagis's infringement, active inducement of infringement, and contribution to the infringement by others of the '882 patent.

162. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Padagis's ANDA Product with its proposed labeling, or any other Padagis drug product that is covered by or the use of which is covered by the '882 patent will infringe, induce the infringement of, and contribute to the infringement by others of the '882 patent and that the claims of the '882 patent are valid.

**COUNT XIX – INFRINGEMENT OF U.S. PATENT NO. 10,821,187**

163. Plaintiff fully incorporate each of the preceding paragraphs 1-162 as if fully set forth herein.

164. Upon information and belief, the use of Padagis's ANDA Product infringes one or more claims of the '187 patent either literally or under the doctrine of equivalents.

165. As a non-limiting example, claim 1 of the '187 patent recites a method of treating acne, comprising administering a foam composition comprising:

- (a) a combination of at least one fatty alcohol and at least one wax; or a combination of at least one fatty alcohol, at least one fatty acid, and at least one wax;
- (b) at least one hydrophobic solvent; at
- (c) a minocycline at a concentration between about 0.2% and about 20% by weight of the composition;

wherein the composition is free of surfactant;

wherein the composition is essentially waterless;

wherein the ration of (1) fatty alcohol to wax or (2) fatty alcohol and fatty acid to wax is between 1:3 and 3:1; and

wherein the wax comprises a mixture of beeswax and hydrogenated castor oil.

166. Upon information and belief, the use of Padagis's ANDA Product infringes claim 1 of the '187 patent literally or under the doctrine of equivalents. The Notice Letter does not contain any factual basis to assert noninfringement of claim 1 of the '187 patent.

167. Padagis's submission of ANDA 216061 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's ANDA Product prior to the expiration of the '187 patent was an act of infringement of the '187 patent under 35 U.S.C. § 271(e)(2)(A).

168. Upon information and belief, Padagis intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 216061, i.e., prior to the expiration of the '187 patent.

169. Upon information and belief, Padagis has knowledge of the claims of the '187 patent. Notwithstanding this knowledge, Padagis has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 216061.

170. Upon information and belief, Padagis plans and intends to, and will, actively induce infringement of the '187 patent when ANDA No. 216061 is approved, and plans and intends to, and will, do so after approval. Padagis will do so with knowledge of the '187 patent and with specific intent to induce infringement of that patent.

171. Upon information and belief, Padagis knows that Padagis's ANDA Product is especially made or adapted for use in infringing the '187 patent, and that Padagis's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Padagis plans and

intends to, and will, contribute to infringement of the '187 patent immediately and imminently upon approval of ANDA No. 216061.

172. The foregoing actions by Padagis constitute and/or will constitute infringement of the '187 patent, active inducement of infringement of the '187 patent, and contributing to the infringement by others of the '187 patent.

173. Unless Padagis is enjoined from infringing the '187 patent, actively inducing infringement of the '187 patent, and contributing to the infringement by others of the '187 patent, Plaintiff will suffer irreparable injury. Plaintiff have no adequate remedy at law.

**COUNT XX – DECLARATORY JUDGMENT  
OF INFRINGEMENT OF THE '187 PATENT**

174. VYNE incorporates each of the preceding paragraphs 1-173 as if fully set forth herein.

175. The Court may declare the rights of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between VYNE on the one hand and Padagis on the other regarding Padagis's infringement, active inducement of infringement, and contribution to the infringement by others of the '187 patent.

176. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Padagis's ANDA Product with its proposed labeling, or any other Padagis drug product that is covered by or the use of which is covered by the '187 patent will infringe, induce the infringement of, and contribute to the infringement by others of the '187 patent and that the claims of the '187 patent are valid.

**COUNT XXI – INFRINGEMENT OF U.S. PATENT NO. 10,398,641**

177. Plaintiff fully incorporate each of the preceding paragraphs 1-176 as if fully set forth herein.

178. Upon information and belief, the use of Padagis's ANDA Product infringes one or more claims of the '641 patent either literally or under the doctrine of equivalents.

179. As a non-limiting example, claim 1 of the '641 patent recites a method for treating acne vulgaris in a subject in need thereof, comprising topically administering to the subject a therapeutically effective amount of a breakable foam obtained from a foamable composition once daily for at least seven consecutive days, wherein the foamable composition comprises:

(a) a hydrophobic vehicle comprising:

(i) about 70% to about 90% by weight of a hydrophobic solvent comprising:

about 50% w/w of soybean oil;

about 16.5% w/w to about 30.7% w/w of coconut oil;

about 3.5% w/w to about 6.5% w/w of cyclomethicone; and

about 1% w/w to about 6% w/w of light mineral oil; and

(ii) about 10% to 22% by weight of a foamer complex comprising:

about 3.5% w/w of cetostearyl alcohol;

about 2% w/w to about 4% w/w of stearic acid;

about 1.8% w/w to about 3.3% w/w of myristyl alcohol;

about 1% to about 3% w/w of beeswax;

about 1% w/w to about 2% w/w of stearyl alcohol; and

about 0.5% w/w to about 1.5% w/w of behenyl alcohol;

(iii) minocycline in about ranging from about 1% w/w to about 4% w/w; and

(b) a propellant in an amount ranging from about 3% to about 25% w/w; and

wherein the foamable composition does not comprise silicon dioxide (SiO<sub>2</sub>)

wherein seven days of topical treatment with the breakable foam at the therapeutically effective amount results in a maximum concentration of minocycline in plasma from the subject of about 2 ng/mL, as measured during a 24 hour period following the last topical administration, and wherein the subject is between 15 years old and 16 years and 11 months old.

180. Upon information and belief, the use of Padagis's ANDA Product infringes claim 1 of the '641 patent literally or under the doctrine of equivalents. The Notice Letter does not contain any factual basis to assert noninfringement of claim 1 of the '641 patent.

181. Padagis's submission of ANDA 216061 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's ANDA Product prior to the expiration of the '641 patent was an act of infringement of the '641 patent under 35 U.S.C. § 271(e)(2)(A).

182. Upon information and belief, Padagis intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 216061, i.e., prior to the expiration of the '641 patent.

183. Upon information and belief, Padagis has knowledge of the claims of the '641 patent. Notwithstanding this knowledge, Padagis has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 216061.

184. Upon information and belief, Padagis plans and intends to, and will, actively induce infringement of the '641 patent when ANDA No. 216061 is approved, and plans and intends to,

and will, do so after approval. Padagis will do so with knowledge of the '641 patent and with specific intent to induce infringement of that patent.

185. Upon information and belief, Padagis knows that Padagis's ANDA Product is especially made or adapted for use in infringing the '641 patent, and that Padagis's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Padagis plans and intends to, and will, contribute to infringement of the '641 patent immediately and imminently upon approval of ANDA No. 216061.

186. The foregoing actions by Padagis constitute and/or will constitute infringement of the '641 patent, active inducement of infringement of the '641 patent, and contributing to the infringement by others of the '641 patent.

187. Unless Padagis is enjoined from infringing the '641 patent, actively inducing infringement of the '641 patent, and contributing to the infringement by others of the '641 patent, Plaintiff will suffer irreparable injury. Plaintiff have no adequate remedy at law.

**COUNT XXII – DECLARATORY JUDGMENT  
OF INFRINGEMENT OF THE '641 PATENT**

188. VYNE incorporates each of the preceding paragraphs 1-187 as if fully set forth herein.

189. The Court may declare the rights of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between VYNE on the one hand and Padagis on the other regarding Padagis's infringement, active inducement of infringement, and contribution to the infringement by others of the '641 patent.

190. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Padagis's ANDA Product with its proposed labeling, or any other Padagis drug product that is covered by or the use of which is covered by the '641 patent will infringe, induce

the infringement of, and contribute to the infringement by others of the '641 patent and that the claims of the '641 patent are valid.

**COUNT XXIII – INFRINGEMENT OF U.S. PATENT NO. 10,849,847**

191. Plaintiff fully incorporate each of the preceding paragraphs 1-190 as if fully set forth herein.

192. Upon information and belief, Padagis's ANDA Product infringes one or more claims of the '847 patent either literally or under the doctrine of equivalents.

193. As a non-limiting example, claim 1 of the '847 patent recites a method for treating acne vulgaris in a subject in need thereof, comprising topically administering to the subject a therapeutically effective amount of a breakable foam obtained from a foamable composition once daily for at least seven consecutive days, wherein the foamable composition comprises:

(a) a hydrophobic vehicle comprising:

(i) about 70% to about 90% by weight of a hydrophobic solvent comprising:

about 35% w/w to about 65% w/w of soybean oil;

about 16.5% w/w to about 30.7% w/w of coconut oil;

about 3.5% w/w to about 6.5% w/w of cyclomethicone;

about 1% w/w to about 6% w/w of light mineral oil;

(ii) about 10% to about 22 % by weight of a foamer complex comprising:

about 2.5% w/w to about 4.6% w/w of cetostearyl alcohol;

about 2% w/w to about 4% w/w of stearic acid;

about 1.8% w/w to about 3.3% w/w of myristyl alcohol;

about 1% w/w to about 3% w/w of hydrogenated castor oil;



about 1% w/w to about 3% w/w of beeswax

about 1% w/w to about 2% w/w of stearyl alcohol; and

about 0.5% w/w to about 1.5% w/w of behenyl alcohol;

(iii) minocycline in an amount ranging from about 1% w/w to about 4% w/w; and

(b) a propellant in an amount ranging from about 3% to about 25% w/w;

Wherein the subject is between 15 years old and 16 years and 11 months old, wherein the foamable composition does not comprise silicon dioxide (SiO<sub>2</sub>), and wherein the minocycline is present in the plasma from the subject at a concentration of at most 1.9 ng/mL before applying the seventh day of treatment with the therapeutically effective amount of the breakable foam.

194. Upon information and belief, the use of Padagis's ANDA Product infringes claim 1 of the '847 patent literally or under the doctrine of equivalents. The Notice Letter does not contain any factual basis to assert noninfringement of claim 1 of the '847 patent.

195. Padagis's submission of ANDA 216061 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Padagis's ANDA Product prior to the expiration of the '847 patent was an act of infringement of the '847 patent under 35 U.S.C. § 271(e)(2)(A).

196. Upon information and belief, Padagis intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 216061, i.e., prior to the expiration of the '847 patent.

197. Upon information and belief, Padagis has knowledge of the claims of the '847 patent. Notwithstanding this knowledge, Padagis has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Padagis's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 216061.

198. Upon information and belief, Padagis plans and intends to, and will, actively induce infringement of the '847 patent when ANDA No. 216061 is approved, and plans and intends to, and will, do so after approval. Padagis will do so with knowledge of the '847 patent and with specific intent to induce infringement of that patent.

199. Upon information and belief, Padagis knows that Padagis's ANDA Product is especially made or adapted for use in infringing the '847 patent, and that Padagis's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Padagis plans and intends to, and will, contribute to infringement of the '847 patent immediately and imminently upon approval of ANDA No. 216061.

200. The foregoing actions by Padagis constitute and/or will constitute infringement of the '847 patent, active inducement of infringement of the '847 patent, and contributing to the infringement by others of the '847 patent.

201. Unless Padagis is enjoined from infringing the '847 patent, actively inducing infringement of the '847 patent, and contributing to the infringement by others of the '847 patent, Plaintiff will suffer irreparable injury. Plaintiff have no adequate remedy at law.

**COUNT XXIV – DECLARATORY JUDGMENT  
OF INFRINGEMENT OF THE '847 PATENT**

202. VYNE incorporates each of the preceding paragraphs 1-201 as if fully set forth herein.

203. The Court may declare the rights of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between VYNE on the one hand and Padagis on the other regarding Padagis's infringement, active inducement of infringement, and contribution to the infringement by others of the '847 patent.

204. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Padagis's ANDA Product with its proposed labeling, or any other Padagis drug product that is covered by or the use of which is covered by the '847 patent will infringe, induce the infringement of, and contribute to the infringement by others of the '847 patent and that the claims of the '847 patent are valid.

**PRAYER FOR RELIEF**

WHEREFORE, VYNE requests the following relief:

(a) A judgment that Padagis has infringed the '139 patent, the '516 patent, the '896 patent, the '700 patent, the '080 patent, the '200 patent, the '512 patent, the '404 patent, the '641 patent, the '882 patent, the '187 patent, and the '847 patent under 35 U.S.C. § 271(e)(2) by Padagis's submission to the FDA of Padagis's ANDA.

(b) A judgment ordering the effective date of any FDA approval of the commercial manufacture, use, or sale of Padagis's ANDA's Product, or any other drug product that infringes or the use of which infringes any of the '139 patent, the '516 patent, the '896 patent, the '700 patent, the '080 patent, the '200 patent, the '512 patent, the '404 patent, the '641 patent, the '882 patent, the '187 patent, and the '847 patent, be not earlier than the latest of the expiration date of the infringed patent(s), inclusive of any extension(s) and additional period(s) of exclusivity.

(c) A preliminary and permanent injunction enjoining Padagis, and all persons acting in concert with Padagis, from the commercial manufacture, use, sale, offer for sale, or importation

into the United States of Padagis's ANDA Product, or any other drug product covered by or whose use is covered by the '139 patent, the '516 patent, the '896 patent, the '700 patent, the '080 patent, the '200 patent, the '512 patent, the '404 patent, the '641 patent, the '882 patent, the '187 patent, and the '847 patent, prior to the expiration of said patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Padagis's ANDA Product, or any other drug product that is covered by or whose use is covered by the '139 patent, the '516 patent, the '896 patent, the '700 patent, the '080 patent, the '200 patent, the '512 patent, the '404 patent, the '641 patent, the '882 patent, the '187 patent, and the '847 patent, prior to the expiration of said patent, inclusive of any extension(s) and additional period(s) of exclusivity;

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

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

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

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August 9, 2021

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Jack B. Blumenfeld*

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