

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DERMIRA, INC. and ROSE U, LLC,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. _____
)	
PERRIGO PHARMA INTERNATIONAL DAC,)	
)	
Defendant.)	

COMPLAINT

Plaintiffs Dermira, Inc. and Rose U, LLC (collectively “Plaintiffs”), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

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 defendant Perrigo Pharma International DAC (“Perrigo”) of an Abbreviated New Drug Application (“ANDA”) No. 214448 to the U.S. Food and Drug Administration (“FDA”) seeking approval to manufacture and sell a Glycopyrronium, Cloth, 2.4% product (“Perrigo’s ANDA Product”) prior to the expiration of U.S. Patent Nos. 8,618,160 (“the ’160 patent”); 9,744,105 (“the ’105 patent”); 10,052,267 (“the ’267 patent”); 8,859,610 (“the ’610 patent”); 9,259,414 (“the ’414 patent”); 10,004,717 (“the ’717 patent”); 10,543,192 (“the ’192 patent”); and 10,548,875 (“the ’875 patent”) (collectively “the Asserted Patents”). Perrigo notified Plaintiffs that it had submitted this ANDA by letters dated September 8, 2020 and September 23, 2020 (each a “Notice Letter” and collectively the “Notice Letters”). Upon information and belief, Perrigo’s ANDA Product will be marketed as a competing product to Qbrexza[®], a product developed by Plaintiffs for the treatment of hyperhidrosis.

PARTIES

2. Dermira, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its corporate offices and place of business at 275 Middlefield Road, Suite 150, Menlo Park, CA 94025. Dermira is a wholly-owned subsidiary of Eli Lilly and Company.

3. Rose U, LLC is a limited liability company organized and existing under the laws of California, having its place of business at 41 Deep Well Lane, Los Altos, CA 94022.

4. Upon information and belief, Perrigo is a corporation organized and existing under the laws of The Republic of Ireland, having a place of business at Treasury Building, Lower Grand Canal Street Dublin, 2 Ireland.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. Upon information and belief, Perrigo is engaged in developing, manufacturing, marketing, selling, and distributing a broad range of generic pharmaceutical products globally. Upon information and belief, a substantial number of these products are marketed throughout the United States, including in the State of Delaware. Upon information and belief, Perrigo operates its manufacturing, marketing, sales, and distribution infrastructure in the United States either itself or via corporate parents, subsidiaries, and affiliates as a vertically integrated company.

7. Upon information and belief, Perrigo has availed itself of the legal protections of the State of Delaware by filing claims or counterclaims affirmatively seeking relief in other prior actions in this Court, including *Anacor Pharm., Inc. v. Ascent Pharm., Inc., Perrigo PLC et al*, 18-1673-RGA (D. Del.). In that case, Perrigo affirmatively filed counterclaims, asking this court to

adjudicate the infringement issues with respect to certain patents asserted in that litigation. Thus, upon information and belief, Perrigo has in the past consented to the jurisdiction of this Court.

8. Upon information and belief, Perrigo regularly does business in Delaware and has engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware.

9. Upon information and belief, Perrigo has sought approval in ANDA No. 214448 to distribute Perrigo's ANDA Product in the United States, including in Delaware and will do so upon approval of ANDA No. 214448. The filing of ANDA No. 214448 is therefore tightly tied, in purpose and planned effect, to the deliberate making of sales in Delaware, and reliably indicates that Perrigo plans to engage in the marketing of Perrigo's ANDA Product in this State.

10. Upon information and belief, with knowledge of the processes described in the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(b) and the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (the "Hatch Waxman Act"), Perrigo directed its Notice Letters to Plaintiffs, one of which is an entity incorporated in Delaware, and alleged in the Notice Letters the invalidity, unenforceability, and/or non-infringement of the Asserted Patents. Upon information and belief, Perrigo deliberately challenged Plaintiffs' patent rights, and knew when it did so that it was triggering a forty-five-day period for Plaintiffs to bring an action for patent infringement under the FDCA.

11. Because one of Plaintiffs is incorporated in Delaware, the injury and consequences of Perrigo's filing of ANDA No. 214448, challenging Plaintiffs' patent rights, are suffered in Delaware. Upon information and belief, Perrigo knew that it was deliberately challenging the patent rights of a Delaware entity and seeking to challenge intellectual property held in Delaware

and that the effects of any successful challenge of the Asserted Patents would be felt by Plaintiffs in Delaware.

12. Upon information and belief, if the ANDA No. 214448 is approved, Perrigo will directly or indirectly market and/or sell Perrigo's ANDA Product within the United States, including in Delaware, consistent with Perrigo's practices for the marketing and distribution of other pharmaceutical products on its own or through its affiliates. Upon information and belief, Perrigo and/or its affiliates regularly do business in Delaware, and their practices with other pharmaceutical products have involved the distribution of Perrigo products, directly or indirectly, throughout the United States, including in Delaware. Upon information and belief, Perrigo's pharmaceutical products are used and/or consumed within and throughout the United States, including Delaware.

13. Upon information and belief, Perrigo and its affiliates derive substantial revenue from pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Perrigo or its affiliates and/or for which Perrigo is the named applicant on approved ANDAs. Upon information and belief, various products for which Perrigo, or its affiliates, is the named applicant on approved ANDAs are available at pharmacies in Delaware.

14. Upon information and belief, if ANDA No. 214448 is approved, Perrigo's ANDA Product, under the direction and control of physicians practicing in Delaware, will be administered to patients of Delaware. These activities, as well as Perrigo's marketing, selling, and/or distributing of Perrigo's ANDA Product, would have a substantial effect within Delaware and would constitute infringement of the Asserted Patents in the event that Perrigo's ANDA Product is approved before the Asserted Patents expire.

15. For the reasons described above, among others, the filing of ANDA No. 214448 was suit-related conduct with a substantial connection to Delaware and this District, the exercise of personal jurisdiction over Perrigo does not offend traditional notions of fair play and substantial justice, and this Court may properly exercise personal jurisdiction over Perrigo.

16. Alternatively, if the exercise of personal jurisdiction over Perrigo in this Court is not held to be proper, then, upon information and belief, Perrigo is not subject to jurisdiction in any state's courts of general jurisdiction, and there is therefore personal jurisdiction over Perrigo in this Court pursuant to Fed. R. Civ. P. 4(k)(2).

17. Upon information and belief and based on the foregoing, Perrigo is a foreign entity subject to this Court's personal jurisdiction and is, therefore, a resident of this District for purposes of venue. As a result, venue is proper in this District.

BACKGROUND

18. Qbrexza[®] is indicated for the topical treatment of primary axillary hyperhidrosis in certain patient populations.

19. Dermira, Inc. sells Qbrexza[®] in the United States pursuant to NDA No. 210361 that has been approved by the FDA.

20. The '160 patent, titled "Topical Glycopyrrolate Formulations," was duly and legally issued on December 31, 2013. A copy of the '160 patent is attached as Exhibit A,

21. Rose U, LLC is the assignee of the '160 patent.

22. Dermira, Inc. is the exclusive licensee of the '160 patent.

23. An actual case or controversy exists between Plaintiffs and Perrigo with respect to infringement of the '160 patent.

24. The '105 patent, titled "Topical Glycopyrrolate Formulations," was duly and legally issued on August 29, 2017. A copy of the '105 patent is attached as Exhibit B,

25. Rose U, LLC is the assignee of the '105 patent.

26. Dermira, Inc. is the exclusive licensee of the '105 patent.

27. An actual case or controversy exists between Plaintiffs and Perrigo with respect to infringement of the '105 patent.

28. The '267 patent, titled "Topical Glycopyrrolate Formulations," was duly and legally issued on August 21, 2018. A copy of the '267 patent is attached as Exhibit C,

29. Rose U, LLC is the assignee of the '267 patent.

30. Dermira, Inc. is the exclusive licensee of the '267 patent.

31. An actual case or controversy exists between Plaintiffs and Perrigo with respect to infringement of the '267 patent.

32. The '610 patent, titled "Crystalline Glycopyrrolate Tosylate," was duly and legally issued on October 14, 2014. A copy of the '610 patent is attached as Exhibit D,

33. Dermira, Inc. is the assignee of the '610 patent.

34. An actual case or controversy exists between Dermira, Inc. and Perrigo with respect to infringement of the '610 patent.

35. The '414 patent, titled "Glycopyrrolate Salts," was duly and legally issued on February 16, 2016. A copy of the '414 patent is attached as Exhibit E,

36. Dermira, Inc. is the assignee of the '414 patent.

37. An actual case or controversy exists between Dermira, Inc. and Perrigo with respect to infringement of the '414 patent.

38. The '717 patent, titled "Glycopyrrolate Salts," was duly and legally issued on June 26, 2018. A copy of the '717 patent is attached as Exhibit F,

39. Dermira, Inc. is the assignee of the '717 patent.

40. An actual case or controversy exists between Dermira, Inc. and Perrigo with respect to infringement of the '717 patent.

41. The '192 patent, titled "Glycopyrrolate Salts," was duly and legally issued on January 28, 2020. A copy of the '192 patent is attached as Exhibit G,

42. Dermira, Inc. is the assignee of the '192 patent.

43. An actual case or controversy exists between Dermira, Inc. and Perrigo with respect to infringement of the '192 patent.

44. The '875 patent, titled "Glycopyrrolate Salts," was duly and legally issued on February 4, 2020. A copy of the '875 patent is attached as Exhibit H,

45. Dermira, Inc. is the assignee of the '875 patent.

46. An actual case or controversy exists between Dermira, Inc. and Perrigo with respect to infringement of the '875 patent.

47. Plaintiffs received Perrigo's first Notice Letter on September 9, 2020. This action is being filed within 45 days of Plaintiffs' receipt of Perrigo's first Notice Letter.

COUNT I
(Infringement of the '160 Patent)

48. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

49. Claim 1 of the '160 patent covers "[a]n individually packaged wipe for the treatment of hyperhidrosis comprising about 0.25 to about 6% w/w of a glycopyrrolate compound, a buffering agent, and an alcohol and water in a weight ratio of about 50:50 to about 70:30, wherein said wipe is individually packaged and contained within a pouch resistant to leakage and the

glycopyrrolate compound degrades by less than 0.5% when stored at 40° C. for 3 months, wherein the buffering agent maintains a pH at about 4.5, and wherein the buffering agent is at about 10 mM to about 20 mM.”

50. Upon information and belief, Perrigo’s ANDA product is covered by one or more claims of the ’160 patent, including at least claim 1.

51. Upon information and belief, the use of Perrigo’s ANDA Product in accordance with and as directed by Perrigo’s proposed labeling for that product will infringe one or more claims of the ’160 patent, including at least claim 1, either literally or under the doctrine of equivalents.

52. Perrigo did not assert in either of its Notice Letters that the use of Perrigo’s ANDA product in accordance with and as directed by Perrigo’s proposed labeling for that product would not meet any claim limitation of any claim of the ’160 patent.

53. Upon information and belief, Perrigo filed as part of ANDA No. 214448 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355(b)(2)(A)(iv), asserting that the claims of the ’160 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Perrigo’s ANDA Product.

54. The purpose of filing ANDA No. 214448 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo’s ANDA Product prior to the expiration of the ’160 patent.

55. Perrigo’s submission of ANDA No. 214448 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo’s ANDA Product prior to the expiration of the ’160 patent is an act of infringement of the ’160 patent under 35 U.S.C. § 271(e)(2)(A).

56. Upon information and belief, Perrigo intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto, *i.e.*, prior to the expiration of the '160 patent.

57. Upon information and belief, Perrigo has knowledge of the claims of the '160 patent at least because the '160 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Dermira's Qbrexza[®] drug product. Notwithstanding this knowledge, Perrigo continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto.

58. Upon information and belief, Perrigo plans and intends to, and will, actively induce infringement of the '160 patent when ANDA No. 214448 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '160 patent. Further upon information and belief, Perrigo plans and intends to, and will, do so immediately and imminently upon approval.

59. Upon information and belief, Perrigo knows that Perrigo's ANDA Product is especially made or adapted for use in infringing the '160 patent, and that Perrigo's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Perrigo plans and intends to, and will, contribute to infringement of the '160 patent immediately and imminently upon approval of ANDA No. 214448 and any amendments thereto.

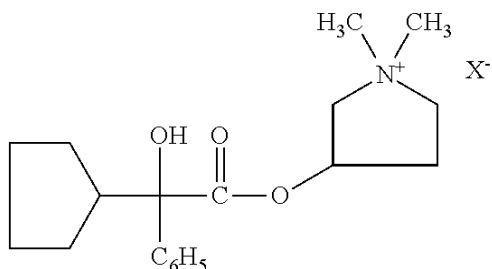
60. The foregoing actions by Perrigo constitute and/or will constitute infringement of the '160 patent, active inducement of infringement of the '160 patent, and contribution to the infringement by others of the '160 patent either literally or under the doctrine of equivalents.

61. Unless Perrigo is enjoined from infringing the '160 patent, actively inducing infringement of the '160 patent, and contributing to the infringement by others of the '160 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II
(Infringement of the '105 Patent)

62. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

63. Claim 1 of the '105 patent covers “[a] glycopyrrolate base solution comprising: about 0.5 to about 4.0% w/w of a glycopyrrolate compound having the following formula:



wherein X⁻ is a pharmaceutically acceptable counter ion salt; ethanol and water in a weight ratio of about 50:50 to about 60:40; and a buffering agent, comprising citric acid and a base selected from the group consisting of sodium citrate and tromethamine, said acid and base at a total concentration of about 0.2 to about 0.5% w/w and at an acid:base ratio sufficient to maintain a pH of the glycopyrrolate base solution of about 3.5 to about 6 for at least nine months at 25° C.

64. Upon information and belief, Perrigo's ANDA product is covered by one or more claims of the '105 patent, including at least claim 1.

65. Upon information and belief, the use of Perrigo's ANDA Product in accordance with and as directed by Perrigo's proposed labeling for that product will infringe one or more

claims of the '105 patent, including at least claim 1, either literally or under the doctrine of equivalents.

66. Perrigo did not assert in either of its Notice Letters that the use of Perrigo's ANDA product in accordance with and as directed by Perrigo's proposed labeling for that product would not meet any claim limitation of any claim of the '105 patent.

67. Upon information and belief, Perrigo filed as part of ANDA No. 214448 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355(b)(2)(A)(iv), asserting that the claims of the '105 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Perrigo's ANDA Product.

68. The purpose of filing ANDA No. 214448 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Product prior to the expiration of the '105 patent.

69. Perrigo's submission of ANDA No. 214448 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Product prior to the expiration of the '105 patent is an act of infringement of the '105 patent under 35 U.S.C. § 271(e)(2)(A).

70. Upon information and belief, Perrigo intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto, *i.e.*, prior to the expiration of the '105 patent.

71. Upon information and belief, Perrigo has knowledge of the claims of the '105 patent at least because the '105 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Dermira's Qbrexza[®] drug product.

Notwithstanding this knowledge, Perrigo continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto.

72. Upon information and belief, Perrigo plans and intends to, and will, actively induce infringement of the '105 patent when ANDA No. 214448 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '105 patent. Further upon information and belief, Perrigo plans and intends to, and will, do so immediately and imminently upon approval.

73. Upon information and belief, Perrigo knows that Perrigo's ANDA Product is especially made or adapted for use in infringing the '105 patent, and that Perrigo's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Perrigo plans and intends to, and will, contribute to infringement of the '105 patent immediately and imminently upon approval of ANDA No. 214448 and any amendments thereto.

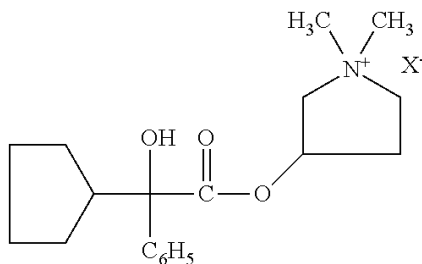
74. The foregoing actions by Perrigo constitute and/or will constitute infringement of the '105 patent, active inducement of infringement of the '105 patent, and contribution to the infringement by others of the '105 patent either literally or under the doctrine of equivalents.

75. Unless Perrigo is enjoined from infringing the '105 patent, actively inducing infringement of the '105 patent, and contributing to the infringement by others of the '105 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT III
(Infringement of the '267 Patent)

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

77. Claim 1 of the '267 patent covers “[a] glycopyrrolate solution comprising: about 0.5 to about 4.0% w/w of a glycopyrrolate compound having the following formula:



wherein X⁻ is a pharmaceutically acceptable counter ion salt; ethanol and water in a weight ratio of about 50:50 to about 60:40; a buffering agent, comprising an acid and a base, said acid and base at a total concentration of about 0.2 to about 0.5% w/w and at an acid:base ratio sufficient to maintain a pH of the glycopyrrolate solution of about 3.5 to about 6 at 25° C.; wherein the acid is citric acid and the base is selected from the group consisting of sodium citrate and tromethamine; wherein the pharmaceutically acceptable counter salt is prepared from an inorganic or organic acid selected from hydrochloric acid, hydrobromic acid, hydrogen fluoride, hydrogen iodide, sulfuric acid, nitric acid, phosphoric acid, acetic acid, propionic acid, glycolic acid, pyruvic acid, oxalic acid, malic acid, malonic acid, succinic acid, maleic acid, fumaric acid, tartaric acid, citric acid, benzoic acid, cinnamic acid, mandelic acid, methanesulfonic acid, ethanesulfonic acid, p-toluene-sulfonic acid, and salicylic acid.”

78. Upon information and belief, Perrigo’s ANDA product is covered by one or more claims of the '267 patent, including at least claim 1.

79. Upon information and belief, the use of Perrigo’s ANDA Product in accordance with and as directed by Perrigo’s proposed labeling for that product will infringe one or more claims of the '267 patent, including at least claim 1, either literally or under the doctrine of equivalents.

80. Perrigo did not assert in either of its Notice Letters that the use of Perrigo's ANDA product in accordance with and as directed by Perrigo's proposed labeling for that product would not meet any claim limitation of any claim of the '267 patent.

81. Upon information and belief, Perrigo filed as part of ANDA No. 214448 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355(b)(2)(A)(iv), asserting that the claims of the '267 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Perrigo's ANDA Product.

82. The purpose of filing ANDA No. 214448 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Product prior to the expiration of the '267 patent.

83. Perrigo's submission of ANDA No. 214448 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Product prior to the expiration of the '267 patent is an act of infringement of the '267 patent under 35 U.S.C. § 271(e)(2)(A).

84. Upon information and belief, Perrigo intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto, *i.e.*, prior to the expiration of the '267 patent.

85. Upon information and belief, Perrigo has knowledge of the claims of the '267 patent at least because the '267 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Dermira's Qbrexza[®] drug product. Notwithstanding this knowledge, Perrigo continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's

ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto.

86. Upon information and belief, Perrigo plans and intends to, and will, actively induce infringement of the '267 patent when ANDA No. 214448 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '267 patent. Further upon information and belief, Perrigo plans and intends to, and will, do so immediately and imminently upon approval.

87. Upon information and belief, Perrigo knows that Perrigo's ANDA Product is especially made or adapted for use in infringing the '267 patent, and that Perrigo's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Perrigo plans and intends to, and will, contribute to infringement of the '267 patent immediately and imminently upon approval of ANDA No. 214448 and any amendments thereto.

88. The foregoing actions by Perrigo constitute and/or will constitute infringement of the '267 patent, active inducement of infringement of the '267 patent, and contribution to the infringement by others of the '267 patent either literally or under the doctrine of equivalents.

89. Unless Perrigo is enjoined from infringing the '267 patent, actively inducing infringement of the '267 patent, and contributing to the infringement by others of the '267 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT IV
(Infringement of the '610 Patent)

90. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

91. Claim 1 of the '610 patent covers "An absorbant pad comprising a pharmaceutically acceptable solution comprising a racemic mixture of (R)-3-((S)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate and (S)-3-((R)-2-

cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate or a solvate thereof and one or more pharmaceutically acceptable additives.”

92. Upon information and belief, Perrigo’s ANDA product is covered by one or more claims of the ’610 patent, including at least claim 1.

93. Upon information and belief, the use of Perrigo’s ANDA Product in accordance with and as directed by Perrigo’s proposed labeling for that product will infringe one or more claims of the ’610 patent, including at least claim 1, either literally or under the doctrine of equivalents.

94. Perrigo did not assert in either of its Notice Letters that the use of Perrigo’s ANDA product in accordance with and as directed by Perrigo’s proposed labeling for that product would not meet any claim limitation of any claim of the ’610 patent.

95. Upon information and belief, Perrigo filed as part of ANDA No. 214448 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355(b)(2)(A)(iv), asserting that the claims of the ’610 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Perrigo’s ANDA Product.

96. The purpose of filing ANDA No. 214448 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo’s ANDA Product prior to the expiration of the ’610 patent.

97. Perrigo’s submission of ANDA No. 214448 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo’s ANDA Product prior to the expiration of the ’610 patent is an act of infringement of the ’610 patent under 35 U.S.C. § 271(e)(2)(A).

98. Upon information and belief, Perrigo intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto, *i.e.*, prior to the expiration of the '610 patent.

99. Upon information and belief, Perrigo has knowledge of the claims of the '610 patent at least because the '610 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Dermira's Qbrexza[®] drug product. Notwithstanding this knowledge, Perrigo continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto.

100. Upon information and belief, Perrigo plans and intends to, and will, actively induce infringement of the '610 patent when ANDA No. 214448 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '610 patent. Further upon information and belief, Perrigo plans and intends to, and will, do so immediately and imminently upon approval.

101. Upon information and belief, Perrigo knows that Perrigo's ANDA Product is especially made or adapted for use in infringing the '610 patent, and that Perrigo's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Perrigo plans and intends to, and will, contribute to infringement of the '610 patent immediately and imminently upon approval of ANDA No. 214448 and any amendments thereto.

102. The foregoing actions by Perrigo constitute and/or will constitute infringement of the '610 patent, active inducement of infringement of the '610 patent, and contribution to the infringement by others of the '610 patent either literally or under the doctrine of equivalents.

103. Unless Perrigo is enjoined from infringing the '610 patent, actively inducing infringement of the '610 patent, and contributing to the infringement by others of the '610 patent, Dermira, Inc. will suffer irreparable injury. Dermira, Inc. has no adequate remedy at law.

COUNT V
(Infringement of the '414 Patent)

104. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

105. Claim 1 of the '414 patent covers “[a] method of treating hyperhidrosis comprising topically administering a therapeutically effective amount of a pharmaceutically acceptable solution of glycopyrrolate tosylate comprising a racemic mixture of (R)-3-((S)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate and (S)-3-((R)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate or solvate thereof to the skin of a mammal, wherein the pH of said pharmaceutically acceptable solution is between 3.5 and 5.5 at 25° C.”

106. Upon information and belief, Perrigo’s ANDA product is covered by one or more claims of the '414 patent, including at least claim 1.

107. Upon information and belief, the use of Perrigo’s ANDA Product in accordance with and as directed by Perrigo’s proposed labeling for that product will infringe one or more claims of the '414 patent, including at least claim 1, either literally or under the doctrine of equivalents.

108. Perrigo did not assert in either of its Notice Letters that the use of Perrigo's ANDA product in accordance with and as directed by Perrigo's proposed labeling for that product would not meet any claim limitation of any claim of the '414 patent.

109. Upon information and belief, Perrigo filed as part of ANDA No. 214448 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355(b)(2)(A)(iv), asserting that the claims of the '414 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Perrigo's ANDA Product.

110. The purpose of filing ANDA No. 214448 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Product prior to the expiration of the '414 patent.

111. Perrigo's submission of ANDA No. 214448 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Product prior to the expiration of the '414 patent is an act of infringement of the '414 patent under 35 U.S.C. § 271(e)(2)(A).

112. Upon information and belief, Perrigo intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto, *i.e.*, prior to the expiration of the '414 patent.

113. Upon information and belief, Perrigo has knowledge of the claims of the '414 patent at least because the '414 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Dermira's Qbrexza® drug product. Notwithstanding this knowledge, Perrigo continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's

ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto.

114. Upon information and belief, Perrigo plans and intends to, and will, actively induce infringement of the '414 patent when ANDA No. 214448 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '414 patent. Further upon information and belief, Perrigo plans and intends to, and will, do so immediately and imminently upon approval.

115. Upon information and belief, Perrigo knows that Perrigo's ANDA Product is especially made or adapted for use in infringing the '414 patent, and that Perrigo's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Perrigo plans and intends to, and will, contribute to infringement of the '414 patent immediately and imminently upon approval of ANDA No. 214448 and any amendments thereto.

116. The foregoing actions by Perrigo constitute and/or will constitute infringement of the '414 patent, active inducement of infringement of the '414 patent, and contribution to the infringement by others of the '414 patent either literally or under the doctrine of equivalents.

117. Unless Perrigo is enjoined from actively inducing infringement of the '414 patent, and contributing to the infringement by others of the '414 patent, Dermira, Inc. will suffer irreparable injury. Dermira, Inc. has no adequate remedy at law.

COUNT VI
(Infringement of the '717 Patent)

118. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

119. Claim 1 of the '717 patent covers "[a]n aqueous glycopyrrolate solution comprising: a racemic mixture of: (R)-3-((S)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate, and (S)-3-((R)-2-cyclopentyl-2-hydroxy-2-

phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate, about 0.15% by weight anhydrous citric acid, about 0.06% by weight sodium citrate dihydrate, and between about 57 to about 59.5% by weight of dehydrated ethanol, wherein: the weight percent of said glycopyrrolate tosylate is between about 1% and about 6%; and the pH of said aqueous glycopyrrolate solution is between 3.5 and 5.5.”

120. Upon information and belief, Perrigo’s ANDA product is covered by one or more claims of the ’717 patent, including at least claim 1.

121. Upon information and belief, the use of Perrigo’s ANDA Product in accordance with and as directed by Perrigo’s proposed labeling for that product will infringe one or more claims of the ’717 patent, including at least claim 1, either literally or under the doctrine of equivalents.

122. Perrigo did not assert in either of its Notice Letters that the use of Perrigo’s ANDA product in accordance with and as directed by Perrigo’s proposed labeling for that product would not meet any claim limitation of any claim of the ’717 patent.

123. Upon information and belief, Perrigo filed as part of ANDA No. 214448 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355(b)(2)(A)(iv), asserting that the claims of the ’717 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Perrigo’s ANDA Product.

124. The purpose of filing ANDA No. 214448 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo’s ANDA Product prior to the expiration of the ’717 patent.

125. Perrigo’s submission of ANDA No. 214448 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo’s ANDA

Product prior to the expiration of the '717 patent is an act of infringement of the '717 patent under 35 U.S.C. § 271(e)(2)(A).

126. Upon information and belief, Perrigo intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto, *i.e.*, prior to the expiration of the '717 patent.

127. Upon information and belief, Perrigo has knowledge of the claims of the '717 patent at least because the '717 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Dermira's Qbrexza[®] drug product. Notwithstanding this knowledge, Perrigo continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto.

128. Upon information and belief, Perrigo plans and intends to, and will, actively induce infringement of the '717 patent when ANDA No. 214448 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '717 patent. Further upon information and belief, Perrigo plans and intends to, and will, do so immediately and imminently upon approval.

129. Upon information and belief, Perrigo knows that Perrigo's ANDA Product is especially made or adapted for use in infringing the '717 patent, and that Perrigo's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Perrigo plans and intends to, and will, contribute to infringement of the '717 patent immediately and imminently upon approval of ANDA No. 214448 and any amendments thereto.

130. The foregoing actions by Perrigo constitute and/or will constitute infringement of the '717 patent, active inducement of infringement of the '717 patent, and contribution to the infringement by others of the '717 patent either literally or under the doctrine of equivalents.

131. Unless Perrigo is enjoined from infringing the '717 patent, actively inducing infringement of the '717 patent, and contributing to the infringement by others of the '717 patent, Dermira, Inc. will suffer irreparable injury. Dermira, Inc. has no adequate remedy at law.

COUNT VII
(Infringement of the '192 Patent)

132. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

133. Claim 1 of the '192 patent covers “[a] pharmaceutically acceptable solution comprising: a racemic mixture of (R)-3-((S)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate and (S)-3-((R)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate, and at least one pharmaceutically acceptable additive; between about 57 and about 59.5% by weight dehydrated ethanol, wherein the weight percent of said racemic mixture of (R)-3-((S)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate and (S)-3-((R)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate is between about 1% and about 6%; and the pH of said pharmaceutically acceptable solution is between 3.5 and 5.5.”

134. Upon information and belief, Perrigo's ANDA product is covered by one or more claims of the '192 patent, including at least claim 1.

135. Upon information and belief, the use of Perrigo's ANDA Product in accordance with and as directed by Perrigo's proposed labeling for that product will infringe one or more

claims of the '192 patent, including at least claim 1, either literally or under the doctrine of equivalents.

136. Perrigo did not assert in either of its Notice Letters that the use of Perrigo's ANDA product in accordance with and as directed by Perrigo's proposed labeling for that product would not meet any claim limitation of any claim of the '192 patent.

137. Upon information and belief, Perrigo filed as part of ANDA No. 214448 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355(b)(2)(A)(iv), asserting that the claims of the '192 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Perrigo's ANDA Product.

138. The purpose of filing ANDA No. 214448 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Product prior to the expiration of the '192 patent.

139. Perrigo's submission of ANDA No. 214448 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Product prior to the expiration of the '192 patent is an act of infringement of the '192 patent under 35 U.S.C. § 271(e)(2)(A).

140. Upon information and belief, Perrigo intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto, *i.e.*, prior to the expiration of the '192 patent.

141. Upon information and belief, Perrigo has knowledge of the claims of the '192 patent at least because the '192 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Dermira's Qbrexza[®] drug product.

Notwithstanding this knowledge, Perrigo continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto.

142. Upon information and belief, Perrigo plans and intends to, and will, actively induce infringement of the '192 patent when ANDA No. 214448 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '192 patent. Further upon information and belief, Perrigo plans and intends to, and will, do so immediately and imminently upon approval.

143. The foregoing actions by Perrigo constitute and/or will constitute infringement of the '192 patent, active inducement of infringement of the '192 patent, and contribution to the infringement by others of the '192 patent either literally or under the doctrine of equivalents.

144. Unless Perrigo is enjoined from infringing the '192 patent, and actively inducing infringement of the '192 patent, Dermira, Inc. will suffer irreparable injury. Dermira, Inc. has no adequate remedy at law.

COUNT VIII
(Infringement of the '875 Patent)

145. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

146. Claim 1 of the '875 patent covers "[a] racemic mixture of (R)-3-((S)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate and (S)-3-((R)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate."

147. Upon information and belief, Perrigo's ANDA product is covered by one or more claims of the '875 patent, including at least claim 1.

148. Upon information and belief, the use of Perrigo's ANDA Product in accordance with and as directed by Perrigo's proposed labeling for that product will infringe one or more claims of the '875 patent, including at least claim 1, either literally or under the doctrine of equivalents.

149. Perrigo did not assert in either of its Notice Letters that the use of Perrigo's ANDA product in accordance with and as directed by Perrigo's proposed labeling for that product would not meet any claim limitation of any claim of the '875 patent.

150. Upon information and belief, Perrigo filed as part of ANDA No. 214448 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355(b)(2)(A)(iv), asserting that the claims of the '875 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Perrigo's ANDA Product.

151. The purpose of filing ANDA No. 214448 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Product prior to the expiration of the '875 patent.

152. Perrigo's submission of ANDA No. 214448 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Product prior to the expiration of the '875 patent is an act of infringement of the '875 patent under 35 U.S.C. § 271(e)(2)(A).

153. Upon information and belief, Perrigo intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto, *i.e.*, prior to the expiration of the '875 patent.

154. Upon information and belief, Perrigo has knowledge of the claims of the '875 patent at least because the '875 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Dermira's Qbrexza[®] drug product. Notwithstanding this knowledge, Perrigo continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto.

155. Upon information and belief, Perrigo plans and intends to, and will, actively induce infringement of the '875 patent when ANDA No. 214448 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '875 patent. Further upon information and belief, Perrigo plans and intends to, and will, do so immediately and imminently upon approval.

156. Upon information and belief, Perrigo knows that Perrigo's ANDA Product is especially made or adapted for use in infringing the '875 patent, and that Perrigo's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Perrigo plans and intends to, and will, contribute to infringement of the '875 patent immediately and imminently upon approval of ANDA No. 214448 and any amendments thereto.

157. The foregoing actions by Perrigo constitute and/or will constitute infringement of the '875 patent, active inducement of infringement of the '875 patent, and contribution to the infringement by others of the '875 patent either literally or under the doctrine of equivalents.

158. Unless Perrigo is enjoined from infringing the '875 patent, actively inducing infringement of the '875 patent, and contributing to the infringement by others of the '875 patent, Dermira, Inc. will suffer irreparable injury. Dermira, Inc. has no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Perrigo has infringed the Asserted Patents and/or will infringe, actively induce infringement of, and/or contribute to infringement by others of the Asserted Patents;

(b) A judgment ordering that the effective date of any FDA approval for Perrigo to make, use, offer for sale, sell, market, distribute, or import Perrigo's ANDA Product, or any product the use of which infringes the Asserted Patents, be not earlier than the expiration date of the Asserted Patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A permanent injunction enjoining Perrigo, and all persons acting in concert with Perrigo, from making, using, selling, offering for sale, marketing, distributing, or importing Perrigo's ANDA Product, or any product the use of which infringes the Asserted Patents, or the inducement of or contribution to any of the foregoing, prior to the expiration date of the Asserted Patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing of Perrigo's ANDA Product, or any product the use of which infringes the Asserted Patents, prior to the expiration date of the Asserted Patents, infringes, will infringe, will actively induce infringement of, and/or will contribute to the infringement by others of the Asserted Patents;

(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 Plaintiffs' 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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