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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

Graceway Pharmaceuticals, LLC and 3M Innovative Properties Company, Plaintiffs, vs. Perrigo Company, Perrigo Israel Pharmaceuticals Ltd., and Nycomed U.S. Inc., Defendants.	Civil Action No.:_____ **COMPLAINT and JURY TRIAL DEMAND**

Plaintiffs, Graceway Pharmaceuticals, LLC and 3M Innovative Properties Company (collectively, "Plaintiffs"), by their undersigned counsel, for their complaint against Defendants, Perrigo Israel Pharmaceuticals Ltd., Perrigo Company and Nycomed U.S. Inc. (collectively, "Defendants"), allege as follows:

Nature of the Case

1. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*

The Parties

2. Plaintiff Graceway Pharmaceuticals, LLC ("Graceway") is a Delaware limited liability company with a principal place of business at 340 Martin Luther King Junior Boulevard, Suite 500, Bristol, Tennessee 37620. Graceway is engaged in the business of developing and marketing innovative pharmaceutical products in the United States.

3. Plaintiff 3M Innovative Properties Company ("3M IPC") is a Delaware corporation with a principal place of business at 3M Center, St. Paul, Minnesota 55144. 3M IPC, an affiliate of 3M Company, is the owner of U.S. Patent No. 7,655,672.

4. On information and belief, Defendant Perrigo Company ("Perrigo") is a Michigan corporation with a principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010. On information and belief, Perrigo is engaged in the manufacture and sale of generic pharmaceutical products.

5. On information and belief, Perrigo conducts business and engages in the manufacture and sale of a range of generic pharmaceutical products within the United States generally and in the State of New Jersey and this Judicial District specifically, including to pharmaceutical wholesalers, distributors and/or warehousing chains within this Judicial District.

6. On information and belief, Perrigo is registered to do business in and conducts business in New Jersey, including through its wholly-owned subsidiary L. Perrigo Company ("L. Perrigo").

7. On information and belief, Defendant Perrigo Israel Pharmaceuticals Ltd. ("Perrigo Israel") is an Israeli company with a corporate headquarters and principal place of business at 29 Lehi Street, Bnei Brak 51200, Israel.

8. On information and belief, Perrigo Israel is a wholly-owned subsidiary of Perrigo.

9. On information and belief, Perrigo Israel is an agent and/or alter ego of Perrigo.

10. On information and belief, Perrigo Israel is under the direction, control and/or influence of Perrigo, both generally and with respect to the particular acts and conduct alleged in this complaint.

11. On information and belief, Perrigo conducts operations through Perrigo Israel.

12. On information and belief, Defendant Nycomed US Inc. ("Nycomed"), formerly known as Altana, Inc. ("Altana"), is a New York company with a principal place of business at 60 Baylis Road, Melville, New York 11747, and a division located in 210 Park Avenue, Florham Park, New Jersey 07932.

13. On information and belief, Nycomed, which operates three divisions in the United States, is in the business of manufacturing and marketing pharmaceuticals, including generic pharmaceuticals.

14. On information and belief, Nycomed conducts business and engages in the manufacture and sale of a range of pharmaceutical products within the United States generally and in the State of New Jersey and this Judicial District specifically, including to pharmaceutical wholesalers, distributors and/or warehousing chains within this Judicial District.

Jurisdiction and Venue

15. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §§ 271 and 281-283. Subject matter jurisdiction is proper under the 28 U.S.C. §§ 1331 and 1338(a).

16. Personal jurisdiction over Perrigo, Perrigo Israel, and Nycomed is proper in this District because of defendants presence in the State of New Jersey and/or their systematic and continuous contacts with the State of New Jersey. Venue is proper under 28 U.S.C. §§ 1391(b)-(c) and 1400(b).

The '672 Patent

17. United States Patent No. 7,655,672 ("the '672 Patent"), entitled "Immune Response Modifier Formulations Containing Oleic Acid and Methods," a true and correct copy of which is appended hereto as Exhibit A, was duly issued on February 2, 2010 to 3M IPC. The

inventors of the '672 Patent are Alexis S. Statham and Robert J. Nelson. The '672 Patent claims, *inter alia*, pharmaceutical creams for topical application to dermal or mucosal surfaces for topical delivery of 1-(2-methylpropyl)-1H-imidazo[4,5-c]quinolin-4-amine ("imiquimod"), wherein the pharmaceutical creams comprise imiquimod and a pharmaceutically acceptable vehicle that includes an oleic acid component.

18. 3M IPC is the record assignee of the '672 Patent. Graceway holds an exclusive license under the '672 Patent, including the right to sublicense, to make, have made, use, develop, have developed, offer for sale, sell, and import products covered by the '672 Patent, and the right to assert, defend, maintain and enforce the '672 Patent.

Background

19. Aldara® (imiquimod) 5% Cream is a topical cream containing imiquimod as the active pharmaceutical ingredient. Aldara® was approved by the United States Food and Drug Administration ("FDA") under New Drug Application ("NDA") 20-723 on February 27, 1997. Graceway is the NDA-holder of NDA 20-723. Aldara® is approved by the FDA for the treatment of: (1) external genital and perianal warts ("EGW") in patients 12 years or older; (2) clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratoses ("AK") on the face or scalp; and (3) biopsy-confirmed, primary superficial basal cell carcinoma ("sBCC") located on the trunk, neck, or extremities (excluding hands and feet).

20. Aldara® 5% Cream, as approved by the FDA, is formulated with imiquimod and a vehicle that includes isostearic acid for topical application to a dermal or mucosal surface for topical delivery of imiquimod. The inventors of the '672 Patent discovered novel imiquimod creams comprising imiquimod and a vehicle that includes an oleic acid component. The oleic acid component, as claimed in the '672 Patent, is directed to an oleic acid component that at least

meets if not exceeds certain United States Pharmacopeia ("USP") monograph compliance stipulations for super refined oleic acid NF.

21. The active pharmaceutical ingredient in Aldara®, imiquimod, is covered by U.S. Patent No. 4,689,338 ("the '338 Patent"). The '338 Patent expired on August 25, 2009. The pediatric exclusivity for the '338 Patent, that was awarded by the FDA under 21 U.S.C. § 355a, expires on February 25, 2010. Thus, the effective expiration of the '338 Patent as to imiquimod is February 25, 2010.

COUNT I
(INFRINGEMENT OF U.S. PATENT 7,655,672 UNDER 35 U.S.C. § 271 BY PERRIGO AND/OR PERRIGO ISRAEL ("Perrigo Defendants")

22. Plaintiffs repeat and incorporate herein by reference the allegations contained in the foregoing paragraphs 1 through 21.

23. On information and belief, Perrigo Israel filed Abbreviated New Drug Application ("ANDA") No. 78-837 with the FDA under 21 U.S.C. § 355(j) seeking approval for an imiquimod topical cream that it alleged was bioequivalent to Aldara®.

24. On information and belief, by this ANDA No. 78-837 filing, Perrigo Israel has evidenced that immediately upon FDA approval, it intends to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of a pharmaceutical cream containing imiquimod and an oleic acid component for topical application to a dermal or mucosal surface for topical delivery of imiquimod to treat, *inter alia*, actinic keratosis (the "Perrigo Proposed ANDA Product").

25. By a letter ("the Perrigo Notice Letter") dated June 28, 2007, Perrigo Israel informed Graceway that it had filed ANDA No. 78-837 with the FDA under 21 U.S.C. § 355(j), containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

26. The Perrigo Notice Letter states that "ANDA [No. 78-837] was submitted under 21 U.S.C. §§ 355 (j)(1) and (2)(A), and contains a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of an imiquimod topical cream formulation product before the expiration date [February 24, 2011] of the '944 patent [Graceway's U.S. Patent No. 5,238,944], which is listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book")".

27. The Perrigo Notice Letter states that the Perrigo Proposed ANDA Product does not contain isostearic acid.

28. On May 15, 2006, Perrigo Israel filed United States Patent Application Serial No. 11/433,471 ("the '471 Patent Application") directed to a pharmaceutical composition for topical application containing imiquimod and oleic acid, among other ingredients. The '471 Patent Application includes six Examples which disclose six different imiquimod pharmaceutical creams. Examples 1-3 and 5-6 of the '471 Patent Application disclose five pharmaceutical creams formulated with imiquimod and 7.4% oleic acid by weight. Example 4 of the '471 Patent Application discloses a pharmaceutical cream formulated with imiquimod and 25% linoleic acid by weight.

29. On information and belief, a pharmaceutical cream formulated with 25% linoleic acid by weight according to Example 4 of the '471 Patent Application is unstable.

30. On information and belief, there are currently only two listings in the FDA's Inactive Ingredients Database ("the FDA's IID") for topical formulations with oleic acid. On information and belief, and as reported in the FDA's IID, the highest FDA approved level of oleic acid for topical formulations with oleic acid is 7.4% in an emulsion or solution (i.e., not a cream). Also on information and belief, and as reported in the FDA's IID, there are two

transdermal patch/film formulations (not creams) that incorporate oleic acid in their patch formulations.

31. On information and belief, standard compendial grade oleic acid NF is an unstable grade of oleic acid that is unsuitable for use as a vehicle in semi-solid topical pharmaceutical formulations, such as creams, lotions, gels or ointments, due to its inherent variability in quality and instability issues, which leads to degradation and rancidity upon exposure to air even at ambient temperature conditions.

32. On information and belief, the United States Pharmacopeia–National Formulary (USP–NF) is a book of public pharmacopeial standards containing standards for medicines, dosage forms, drug substances, excipients, medical devices, and dietary supplements.

33. On information and belief, the USP-NF is a combination of two official compendia, the United States Pharmacopeia (USP) and the National Formulary (NF).

34. On information and belief, the FDA designates the USP–NF as the official compendia for drugs marketed in the United States.

35. On information and belief, excipient monographs, such as for oleic acid, are in the NF.

36. On information and belief, any drug product, including pharmaceutical creams, marketed by the Perrigo Defendants in the United States must conform to at least certain of the standards set forth in the USP–NF.

37. On information and belief, the Perrigo Proposed ANDA Product is formulated with imiquimod and a vehicle that includes an oleic acid component.

38. On information and belief, the Perrigo Proposed ANDA Product is formulated with imiquimod and a vehicle that includes an oleic acid component that conforms to at least

certain of the standards set forth in the monograph compliance stipulations for super refined oleic acid NF.

39. On information and belief, the Perrigo Proposed ANDA Product is formulated with 5% imiquimod and a vehicle that includes a 7.4% oleic acid component by weight.

40. On information and belief, the Perrigo Proposed ANDA Product is formulated with 5% imiquimod and a vehicle that includes a 7.4% oleic acid component that conforms to at least certain of the monograph compliance stipulations for super refined oleic acid NF by weight.

41. On information and belief, once the Perrigo Defendants receive FDA approval for the Perrigo Proposed ANDA Product, they will infringe one or more claims of the '672 Patent by manufacturing, using, offering for sale or selling the Perrigo Proposed ANDA Product, within the United States, or importing into the United States the Perrigo Proposed ANDA Product.

42. Upon information and belief, FDA approval of the Perrigo Proposed ANDA Product is imminent.

43. The Perrigo Notice Letter evidenced the Perrigo Defendants' intent to market the Perrigo Proposed ANDA Product (its generic imiquimod product) immediately following the effective expiration [with pediatric exclusivity] of the '338 Patent on February 25, 2010.

44. Upon information and belief, Perrigo Defendants sought approval of the Perrigo Proposed ANDA Product from the FDA to immediately commercialize the Perrigo Proposed ANDA Product on February 25, 2010, the effective expiration date [with pediatric exclusivity] of the '338 Patent.

45. On information and belief, based on standard industry practice, prior to receiving FDA approval, the Perrigo Defendants will have engaged in activities in preparation for manufacturing, distributing, offering to sell, selling and importing the Perrigo Proposed ANDA

Product in the United States.

46. On information and belief, such activities have already infringed, or imminently will infringe, one or more claims of the '672 Patent.

47. Unless the Perrigo Defendants are enjoined from infringing the '672 Patent, Plaintiffs will suffer substantial and irreparable injury for which Plaintiffs have and will have no adequate remedy at law.

COUNT II
(INFRINGEMENT OF U.S. PATENT 7,655,672 UNDER 35 U.S.C. § 271 BY NYCOMED)

48. Plaintiffs repeat and incorporate herein by reference the allegations contained in the foregoing paragraphs 1 through 47 herein.

49. On information and belief, Nycomed filed ANDA No. 78-548 with the FDA under 21 U.S.C. § 355(j) seeking approval for an imiquimod topical cream that Nycomed alleged was bioequivalent to Aldara®.

50. On information and belief, by this ANDA filing, Nycomed has evidenced that immediately after approval, it intends to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of a pharmaceutical cream containing imiquimod and an oleic acid component for topical application to a dermal or mucosal surface for topical delivery of imiquimod to treat, *inter alia*, actinic keratosis (the "Nycomed Proposed ANDA Product").

51. By a letter ("the Nycomed Notice Letter") dated January 10, 2007, Nycomed informed Graceway that it had filed ANDA No. 78-548 with the FDA under 21 U.S.C. § 355(j), containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The Nycomed Notice Letter states that the Nycomed Proposed ANDA Product contains imiquimod and oleic acid.

52. On information and belief, there are currently only two listings in the FDA's

Inactive Ingredients Database ("the FDA's IID") for topical formulations with oleic acid. On information and belief, and as reported in the FDA's IID, the highest FDA approved level of oleic acid for topical formulations with oleic acid is 7.4% in an emulsion or solution (i.e., not a cream). Also on information and belief, and as reported in the FDA's IID, there are two transdermal patch/film formulations (not creams) that incorporate oleic acid in their patch formulations.

53. On information and belief, standard compendial grade oleic acid NF is an unstable grade of oleic acid that is unsuitable for use as a vehicle in semi-solid topical pharmaceutical formulations, such as creams, lotions, gels or ointments, due to its inherent variability in quality and instability issues, which leads to degradation and rancidity upon exposure to air even at ambient temperature conditions.

54. On information and belief, the United States Pharmacopeia–National Formulary (USP–NF) is a book of public pharmacopeial standards containing standards for medicines, dosage forms, drug substances, excipients, medical devices, and dietary supplements.

55. On information and belief, the USP-NF is a combination of two official compendia, the United States Pharmacopeia (USP) and the National Formulary (NF).

56. On information and belief, the FDA designates the USP–NF as the official compendia for drugs marketed in the United States.

57. On information and belief, excipient monographs, such as for oleic acid, are in the NF.

58. On information and belief, any drug product, including pharmaceutical creams, marketed by the Nycomed Defendants in the U.S. must conform to at least certain of the standards set forth in the USP–NF.

59. On information and belief, the Nycomed Proposed ANDA Product is formulated with imiquimod and a vehicle that includes an oleic acid component.

60. On information and belief, the Nycomed Proposed ANDA Product is formulated with imiquimod and a vehicle that includes an oleic acid component that conforms to at least certain of the monograph compliance stipulations for super refined oleic acid NF.

61. The Nycomed Notice Letter states that the Nycomed Proposed ANDA Product is formulated with 5% imiquimod and a vehicle that includes a 25% oleic acid component.

62. On information and belief, the Nycomed Proposed ANDA Product is formulated with 5% imiquimod and a vehicle that includes a 25% oleic acid component that conforms to at least certain of the monograph compliance stipulations for super refined oleic acid NF by weight.

63. On information and belief, once Nycomed receives FDA approval for the Nycomed Proposed ANDA Product, Nycomed will infringe one or more claims of the '672 Patent by manufacturing, using, offering for sale, selling and/or importing the Nycomed Proposed ANDA Product in the United States.

64. Upon information and belief, FDA approval of the Nycomed Proposed ANDA Product is imminent.

65. On information and belief, the Nycomed Notice Letter evidences Nycomed's intent to market the Nycomed Proposed ANDA Product (its generic imiquimod product) immediately following the effective expiration date [with pediatric exclusivity] of the '338 Patent on February 25, 2010.

66. Upon information and belief, Nycomed sought approval of the Nycomed Proposed ANDA Product from the FDA to immediately commercialize the Nycomed Proposed ANDA Product upon the effective expiration date [with pediatric exclusivity] of the '338 Patent,

67. On information and belief, based on standard industry practice, prior to receiving FDA approval, Nycomed will have engaged in activities in preparation for manufacturing, distributing, offering to sell, selling and importing the Nycomed Proposed ANDA Product in the United States.

68. On information and belief, such activities have already infringed, or imminently will infringe, one or more claims of the '672 Patent.

69. Unless Nycomed is enjoined from infringing of the '672 Patent, Plaintiffs will suffer substantial and irreparable injury, for which Plaintiffs have and will have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that making, using, selling, or offering to sell the Perrigo Proposed ANDA Product for which the Perrigo Defendants seek FDA approval under ANDA No. 78-837, within the United States, or importing into the United States the Perrigo Proposed ANDA Product for which the Perrigo Defendants seek FDA approval under ANDA No. 78-837 infringes one or more claims of the '672 Patent;

(b) A declaratory judgment pursuant to 28 U.S.C. § 2201 *et seq.* that making, using, selling or offering to sell the Perrigo Proposed ANDA Product for which the Perrigo Defendants seek FDA approval under ANDA No. 78-837, within the United States, or importing into the United States the Perrigo Proposed ANDA Product for which the Perrigo Defendants seek FDA approval under ANDA No. 78-837 will infringe one or more claims of the '672 Patent;

(c) A preliminary and permanent injunction restraining and enjoining against any infringement by Defendants Perrigo, their officers, agents, attorneys, or employees, or those acting in privity or concert with them, of the '672 Patent through the manufacture, use, sale, or

offer for sale, within the United States, the Perrigo Proposed ANDA Product for which the Perrigo defendants seek FDA approval under ANDA No. 78-837, or the importation into the United States of the Perrigo Proposed ANDA Product for which the Perrigo Defendants seek FDA approval under ANDA No. 78-837;

(d) A judgment that making, using, selling, or offering to sell the Nycomed Proposed ANDA Product for which Nycomed seeks FDA approval under ANDA No. 78-548, within the United States, or importing into the United States the Nycomed Proposed ANDA Product for which Nycomed seeks FDA approval under ANDA No. 78-548 infringes one or more claims of the '672 Patent;

(e) A declaratory judgment pursuant to 28 U.S.C. § 2201 *et seq.* that making, using, selling or offering to sell the Nycomed Proposed ANDA Product for which Nycomed seeks FDA approval under ANDA No. 78-548, within the United States, or importing into the United States the Nycomed Proposed ANDA Product for which Nycomed seeks FDA approval under ANDA No. 78-548 will infringe one or more claims of the '672 Patent;

(f) A preliminary and permanent injunction restraining and enjoining against any infringement by Nycomed, its officers, agents, attorneys, or employees, or those acting in privity or concert with Nycomed, of the '672 Patent through the manufacture, use, sale, or offer for sale, within the United States, the Nycomed Proposed ANDA Product for which Nycomed seeks FDA approval under ANDA No. 78-548, or the importation into the of United States the Nycomed Proposed ANDA Product for which Nycomed seeks FDA approval under ANDA No. 78-548;

(g) Attorneys' fees in this action under 35 U.S.C. § 285;

(h) Damages and costs of suit;

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

JURY DEMAND

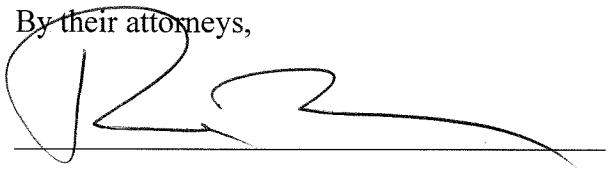
Plaintiffs hereby demand a trial by jury on all issues and claims so triable.

Dated: Madison, New Jersey
February 23, 2010

Respectfully submitted,

Graceway Pharmaceuticals, LLC,
and 3M Innovative Properties Company,

By their attorneys,



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