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U.S. DISTRICT COURT
INDIANAPOLIS DIVISION
2013 MAY 24 PM 3:20
SOUTHERN DISTRICT
OF INDIANA
LAURA A. BRIGGS
CLERK

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,
ELI LILLY EXPORT S.A. AND
ACRUX DDS PTY LTD.,

Plaintiffs,

v.

PERRIGO COMPANY AND
PERRIGO ISRAEL PHARMACEUTICALS LTD.,

Defendants.

Case No.

1:13-cv-0851 SEB-MJD

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Eli Lilly and Company ("Lilly"), Eli Lilly Export S.A., and Acrux DDS Pty Ltd. ("Acrux") file this Complaint for patent infringement against Perrigo Company and Perrigo Israel Pharmaceuticals Ltd. (collectively "Defendants") under 35 U.S.C. § 271. This patent action concerns the pharmaceutical drug product Axiron®.

THE PARTIES

1. Lilly is an Indiana corporation that has its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Lilly is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

2. Eli Lilly Export S.A. is a Swiss corporation that has its corporate office at 16 Chemin des Coquelicots, The Air Centre, 1214 Vernier/Geneva, Switzerland. Eli Lilly Export S.A. is a wholly owned subsidiary of Lilly.

3. Acrux is an Australian corporation that has its corporate offices and principal place of business at 103-113 Stanley Street, West Melbourne VIC 3003, Australia. Acrux is engaged in the development and commercialization of pharmaceutical products for sale throughout the world.

4. Perrigo Company is a Michigan corporation with its principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010. Perrigo Company is a generic pharmaceutical company that develops, manufactures, markets, and distributes generic pharmaceutical products for sale in the State of Indiana and throughout the United States.

5. Perrigo Israel Pharmaceuticals Ltd. ("Perrigo Israel") is an Israeli corporation with its principal place of business at 29 Lehi Street, Bnei Brak 51200, Israel. Perrigo Israel is a wholly-owned subsidiary of Perrigo Company.

6. Perrigo Israel is a generic pharmaceutical company that develops, manufactures, markets, and distributes generic pharmaceutical products for sale in the State of Indiana and throughout the United States in concert with its parent company Perrigo Company and related companies.

NATURE OF THE ACTION

7. This is an action for infringement of U.S. Patent Nos. 8,435,944 ("the '944 patent"), 8,419,307 ("the '307 patent"), and 8,177,449 ("the '449 patent"). This action relates to Abbreviated New Drug Application ("ANDA") No. 204255 submitted in the name of Perrigo Israel to the U.S. Food and Drug Administration ("FDA") for approval to market a generic version of Lilly's Axiron® (testosterone) product, which constitutes an action of infringement

under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(e)(2).

SUBJECT MATTER JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

10. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

PERSONAL JURISDICTION

11. The Court has personal jurisdiction over Defendants because they regularly and continuously transact business within the State of Indiana. Defendants market and sell pharmaceutical products throughout the United States, including the State of Indiana. Defendants derive substantial revenue from Indiana drug sales and have availed themselves of the privilege of conducting business within the State of Indiana.

12. According to the website for Perrigo Company and its subsidiaries (collectively, "Perrigo"), "Perrigo develops, manufactures and distributes over-the-counter (OTC) and generic prescription (R_x) pharmaceuticals, infant formulas, nutritional products, dietary supplements and active pharmaceutical ingredients (API). The Company is the world's largest manufacturer of OTC pharmaceutical products for the store brand market. The Company's primary markets and locations of logistics operations have evolved over the years to include the United States . . . ."

13. Perrigo's 2012 Annual Report states that Perrigo "operates through several wholly owned subsidiaries," including Perrigo Israel. As described in its Annual Report, Perrigo has "four reportable segments, aligned primarily by type of product: Consumer Healthcare, Nutritionals, R_x Pharmaceuticals and API." Perrigo's Annual Report explains that "[e]ach of

these business segments share Research & Development ("R&D"), Supply Chain, Information Technology, Finance, Human Resources, Legal and Quality services, all of which are directed out of the Company's headquarters in Allegan, Michigan."

14. Perrigo Israel is part of Perrigo's R_x pharmaceuticals segment.

15. According to Perrigo's 2012 Annual Report, "[t]he Consumer Healthcare segment currently markets over 2,100 store brand products, with over 9,000 stock-keeping units ("SKUs"), to over 800 customers." In addition, for the Consumer Healthcare segment, "[t]he Company's U.S.-based customers are major national and regional retail drug, supermarket and mass merchandise chains, including Wal-Mart, CVS, Walgreens, Kroger, Target, Dollar General, Rite Aid, Sam's Club and Costco, and major wholesalers, including McKesson, Cardinal Health and AmerisourceBergen."

16. According to Perrigo's 2012 Annual Report, "[t]he R_x Pharmaceuticals segment develops, manufactures and markets a portfolio of generic prescription drugs for the U.S. market. The Company defines this portfolio as predominantly 'extended topical' and specialty as it encompasses a broad array of topical dosage forms such as creams, ointments, lotions, gels, shampoos, foams, suppositories, sprays, liquids, suspensions, solutions and powders. The portfolio also includes select controlled substances, injectables, hormones, oral liquids and oral solid dosage forms." The 2012 Annual Report further states that "[t]he R_x Pharmaceuticals segment currently markets approximately 400 generic prescription products, with almost 1,000 SKUs, to approximately 300 customers." In addition, for the R_x Pharmaceuticals segment, "[t]he Company's U.S.-based customers are major wholesalers, including Cardinal Health, McKesson and AmerisourceBergen, as well as national and regional retail drug, supermarket and mass merchandise chains, including Walgreens, Wal-Mart, CVS, Rite Aid, Kroger and Safeway.

Generic prescription drugs are sold to the consumer through the pharmacy counter of predominantly the same retail outlets as OTC pharmaceuticals and nutritional products."

17. A wholly owned subsidiary of Perrigo Company, Perrigo Sales Corporation (515 Eastern Avenue, Allegan, MI 40910), has been granted a Certificate of Authority from the Indiana Secretary of State.

18. Perrigo Company, directly or through related companies, has engaged in substantial and continuous contacts with Indiana that satisfy due process and confer personal jurisdiction over Perrigo Company in Indiana on the basis of general jurisdiction.

19. Perrigo Company, either directly or through wholesalers, sells products to national and regional retail drug, supermarket, and mass merchandise chains in Indiana, and Perrigo Company derives substantial revenue from these sales.

20. Perrigo Israel, directly or in concert with related companies, has engaged in substantial and continuous contacts with Indiana that satisfy due process and confer personal jurisdiction over Perrigo Israel in Indiana on the basis of general jurisdiction.

21. Perrigo Israel develops and manufactures pharmaceutical products for the United States market, including the State of Indiana. These products include cetirizine tablets and syrup, clobetasol foam, halobetasol ointment and cream, imiquimod cream, and mesalamine rectal suspension enema, which are all among Perrigo's major pharmaceutical products, according to Perrigo's 2012 Annual Report. Perrigo Israel, directly, through wholesalers, or in concert with related companies, sells products to national and regional retail drug, supermarket, and mass merchandise chains in Indiana, and Perrigo Israel derives substantial revenue from these sales.

22. Perrigo Company acts as the agent and official submitter to the FDA of Perrigo Israel's ANDA No. 204255 at issue in this case. Perrigo Company participated in the preparation and submission of ANDA No. 204255 and will benefit directly and indirectly upon the approval of ANDA No. 204255.

FACTUAL BACKGROUND

A. Axiron®

23. Lilly is the holder of approved New Drug Application ("NDA") No. 022504 for the manufacture and sale of testosterone metered transdermal solution, 30mg/1.5mL used to treat males for conditions associated with a deficiency or absence of endogenous testosterone. Lilly markets and sells testosterone metered transdermal solution, 30mg/1.5mL under the trade name Axiron®. Axiron® was approved by the FDA on November 23, 2010.

B. The '944 Patent

24. United States Patent No. 8,435,944 ("the '944 patent"), entitled "Method and Composition for Transdermal Drug Delivery," was duly and legally issued by the United States Patent and Trademark Office ("PTO") on May 7, 2013. The '944 patent claims, *inter alia*, methods of increasing the testosterone blood level of an adult male comprising applying a transdermal drug delivery composition that contains testosterone. The '944 patent is listed in the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") in connection with Axiron®. A true and correct copy of the '944 patent is attached as Exhibit A. Since its date of issue, Acrux has been, and continues to be, the owner of the '944 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron® under the '944 patent. Eli Lilly Export S.A. has licensed its rights in the '944 patent to Lilly.

C. The '307 Patent

25. United States Patent No. 8,419,307 ("the '307 patent"), entitled "Spreading Implement," was duly and legally issued by the PTO on April 16, 2013. The '307 patent claims, *inter alia*, a method of increasing the testosterone blood level of a person in need thereof comprising applying a liquid pharmaceutical composition that contains testosterone. The '307 patent is listed in the Orange Book in connection with Axiron®. A true and correct copy of the '307 patent is attached as Exhibit B. Since its date of issue, Acrux has been, and continues to be, the owner of the '307 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron® under the '307 patent. Eli Lilly Export S.A. has licensed its rights in the '307 patent to Lilly.

D. The '449 Patent

26. United States Patent No. 8,177,449 ("the '449 patent") entitled "Spreading Implement," was duly and legally issued by the PTO on May 15, 2012. The '449 patent claims, *inter alia*, a method of transdermal administration of a physiologically active agent. A true and correct copy of the '449 patent is attached as Exhibit C. Since its date of issue, Acrux has been, and continues to be, the owner of the '449 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron® under the '449 patent. Eli Lilly Export S.A. has licensed its rights in the '449 patent to Lilly.

E. Infringement by Perrigo

27. Defendants filed or caused to be filed with the FDA ANDA No. 204255 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of "Testosterone Metered Transdermal Solution, 30mg/1.5mL" ("Perrigo's Generic Product") in the United States before the expiration of the '944, '307, and '449 patents.

28. Perrigo Company and Perrigo Israel acted in concert to prepare and submit ANDA No. 204255.

29. Defendants amended ANDA No. 204255 to contain certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certifications"), alleging that the claims of the '944, '307, and '449 patents are invalid, unenforceable, and/or would not be infringed by Perrigo's Generic Product.

30. Defendants sent or caused to be sent to Lilly a letter dated September 7, 2012 ("Perrigo's September 7, 2012, Notice Letter"), notifying Lilly that Defendants' ANDA No. 204255 includes a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of Perrigo's Generic Product before the expiration of the '449 patent, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B). Perrigo's September 7, 2012, Notice Letter states: "Perrigo alleges, and has certified to FDA, that in Perrigo's opinion and to the best of its knowledge, the '449 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, or importation of the drug product described in Perrigo's ANDA."

31. Defendants sent or caused to be sent to Lilly a letter dated April 16, 2013 ("Perrigo's April 16, 2013, Notice Letter"), notifying Lilly that Defendants' ANDA No. 204255 includes a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of Perrigo's Generic Product before the expiration of the '307 patent, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B). Perrigo's April 16, 2013, Notice Letter states: "Perrigo alleges, and has certified to FDA, that in Perrigo's opinion and to the best of its knowledge, the '307 patent is invalid, unenforceable, and/or will not be infringed

by the commercial manufacture, use, sale, or importation of the drug product described in Perrigo's ANDA."

32. Defendants sent or caused to be sent to Lilly a letter dated May 9, 2013 ("Perrigo's May 9, 2013, Notice Letter"), notifying Lilly that Defendants' ANDA No. 204255 includes a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of Perrigo's Generic Product before the expiration of the '944 patent, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B). Perrigo's May 9, 2013, Notice Letter states: "Perrigo alleges, and has certified to FDA, that in Perrigo's opinion and to the best of its knowledge, the '944 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, or importation of the drug product described in Perrigo's ANDA."

33. The submission of ANDA No. 204255 to the FDA constitutes infringement by Defendants of the '944, '307, and '449 patents under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, sale, offer for sale, or importation of Perrigo's Generic Product would infringe the '944, '307, and '449 patents under 35 U.S.C. § 271(a), (b), and/or (c).

34. Defendants know and intend that physicians will prescribe and patients will take Perrigo's Generic Product for which approval is sought in ANDA No. 204255 and therefore, will infringe at least one claim of the patents in suit.

35. Defendants had knowledge of the patents-in-suit and by their promotional activities associated with Perrigo's Generic Product, know or should know that they will aid and abet another's direct infringement of at least one of the claims of the patents in suit either literally or under the doctrine of equivalents.

36. Defendants plan to make, use, sell, offer to sell and/or import Perrigo's Generic Product for uses that will infringe the patents in suit. Perrigo's Generic Product is a material part of these infringing uses and has no substantial non-infringing uses.

37. Plaintiffs commenced this action within 45 days of receiving Perrigo's April 16, 2013 Notice Letter and Perrigo's May 9, 2013 Notice Letter.

COUNT I FOR PATENT INFRINGEMENT
(Direct Infringement of U.S. Patent No. 8,435,944)

38. Plaintiffs incorporate by reference and reallege Paragraphs 1-37 above as though fully restated herein.

39. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 204255 to the FDA seeking approval of Perrigo's Generic Product before expiration of the '944 patent was an act of infringement of the '944 patent by Defendants.

40. If ANDA No. 204255 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Perrigo's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '944 patent under 35 U.S.C. § 271.

41. Unless Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '944 patent. Plaintiffs do not have an adequate remedy at law.

COUNT II FOR PATENT INFRINGEMENT
(Inducement To Infringe U.S. Patent No. 8,435,944)

42. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 41 above as though fully restated herein.

43. Defendants have knowledge of the '944 patent.

44. Upon FDA approval of ANDA No. 204255, Defendants will intentionally encourage acts of direct infringement of the '944 patent by others, with knowledge that their acts are encouraging infringement.

COUNT III FOR PATENT INFRINGEMENT
(Contributory Infringement of U.S. Patent No. 8,435,944)

45. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 44 above as though fully restated herein.

46. If ANDA No. 204255 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Perrigo's Generic Product.

47. Defendants have had and continue to have knowledge that Perrigo's Generic Product is especially adapted for a use that infringes the '944 patent.

48. Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Perrigo's Generic Product.

COUNT IV FOR PATENT INFRINGEMENT
(Direct Infringement of U.S. Patent No. 8,419,307)

49. Plaintiffs incorporate by reference and reallege Paragraphs 1-48 above as though fully restated herein.

50. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 204255 to the FDA seeking approval of Perrigo's Generic Product before expiration of the '307 patent was an act of infringement of the '307 patent by Defendants.

51. If ANDA No. 204255 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Perrigo's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '307 patent under 35 U.S.C. § 271.

52. Unless Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '307 patent. Plaintiffs do not have an adequate remedy at law.

COUNT V FOR PATENT INFRINGEMENT
(Inducement To Infringe U.S. Patent No. 8,419,307)

53. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 52 above as though fully restated herein.

54. Defendants have knowledge of the '307 patent.

55. Upon FDA approval of ANDA No. 204255, Defendants will intentionally encourage acts of direct infringement of the '307 patent by others, with knowledge that their acts are encouraging infringement.

COUNT VI FOR PATENT INFRINGEMENT
(Contributory Infringement of U.S. Patent No. 8,419,307)

56. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 55 above as though fully restated herein.

57. If ANDA No. 204255 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Perrigo's Generic Product.

58. Defendants have had and continue to have knowledge that Perrigo's Generic Product is especially adapted for a use that infringes the '307 patent.

59. Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Perrigo's Generic Product.

COUNT VII FOR PATENT INFRINGEMENT
(Direct Infringement of U.S. Patent No. 8,177,449)

60. Plaintiffs incorporate by reference and reallege Paragraphs 1-59 above as though fully restated herein.

61. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 204255 to the FDA seeking approval of Perrigo's Generic Product before expiration of the '449 patent was an act of infringement of the '449 patent by Defendants.

62. If ANDA No. 204255 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Perrigo's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '449 patent under 35 U.S.C. § 271.

63. Unless Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '449 patent. Plaintiffs do not have an adequate remedy at law.

COUNT VIII FOR PATENT INFRINGEMENT
(Inducement To Infringe U.S. Patent No. 8,177,449)

64. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 63 above as though fully restated herein.

65. Defendants have knowledge of the '449 patent.

66. Upon FDA approval of ANDA No. 204255, Defendants will intentionally encourage acts of direct infringement of the '449 patent by others, with knowledge that their acts are encouraging infringement.

COUNT IX FOR PATENT INFRINGEMENT
(Contributory Infringement of U.S. Patent No. 8,177,449)

67. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 66 above as though fully restated herein.

68. If ANDA No. 204255 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Perrigo's Generic Product.

69. Defendants have had and continue to have knowledge that Perrigo's Generic Product is especially adapted for a use that infringes the '449 patent.

70. Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Perrigo's Generic Product.

COUNT X FOR DECLARATORY JUDGMENT
(Infringement of U.S. Patent No. 8,435,944)

71. Plaintiffs incorporate by reference and reallege Paragraphs 1-70 above as though fully restated herein.

72. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

73. Defendants submitted ANDA No. 204255, seeking authorization to commercially manufacture, use, offer for sale, and sell Perrigo's Generic Product in the United States. Defendants' Generic Product has no substantial non-infringing uses.

74. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Perrigo's Generic Product prior to expiration of the '944 patent.

75. Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Perrigo's Generic Product upon receipt of final FDA approval of ANDA No. 204255, unless enjoined by the Court.

76. Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Perrigo's Generic Product would infringe one or more claims of the '944 patent under 35 U.S.C. § 271(a), (b), and/or (c).

77. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Perrigo's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '944 patent.

78. Defendants have had and continue to have knowledge that Perrigo's Generic Product is especially adapted for a use that infringes the '944 patent.

79. Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Perrigo's Generic Product.

80. There is a justiciable case or controversy between Plaintiffs and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Perrigo's Generic Product according to ANDA No. 204255 would infringe one or more claims of the '944 patent.

81. If Defendants' infringement of the '944 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

COUNT XI FOR DECLARATORY JUDGMENT
(Infringement of U.S. Patent No. 8,419,307)

82. Plaintiffs incorporate by reference and reallege Paragraphs 1-81 above as though fully restated herein.

83. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

84. Defendants submitted ANDA No. 204255, seeking authorization to commercially manufacture, use, offer for sale, and sell Perrigo's Generic Product in the United States. Defendants' Generic Product has no substantial non-infringing uses.

85. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Perrigo's Generic Product prior to expiration of the '307 patent.

86. Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Perrigo's Generic Product upon receipt of final FDA approval of ANDA No. 204255, unless enjoined by the Court.

87. Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Perrigo's Generic Product would infringe one or more claims of the '307 patent under 35 U.S.C. § 271(a), (b), and/or (c).

88. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Perrigo's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '307 patent.

89. Defendants have had and continue to have knowledge that Perrigo's Generic Product is especially adapted for a use that infringes the '307 patent.

90. Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Perrigo's Generic Product.

91. There is a justiciable case or controversy between Plaintiffs and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Perrigo's Generic Product according to ANDA No. 204255 would infringe one or more claims of the '307 patent.

92. If Defendants' infringement of the '307 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

COUNT XII FOR DECLARATORY JUDGMENT
(Infringement of U.S. Patent No. 8,177,449)

93. Plaintiffs incorporate by reference and reallege Paragraphs 1-92 above as though fully restated herein.

94. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

95. Defendants submitted ANDA No. 204255, seeking authorization to commercially manufacture, use, offer for sale, and sell Perrigo's Generic Product in the United States. Defendants' Generic Product has no substantial non-infringing uses.

96. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Perrigo's Generic Product prior to expiration of the '449 patent.

97. Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Perrigo's Generic Product upon receipt of final FDA approval of ANDA No. 204255, unless enjoined by the Court.

98. Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Perrigo's Generic Product would infringe one or more claims of the '449 patent under 35 U.S.C. § 271(a), (b), and/or (c).

99. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Perrigo's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '449 patent.

100. Defendants have had and continue to have knowledge that Perrigo's Generic Product is especially adapted for a use that infringes the '449 patent.

101. Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Perrigo's Generic Product.

102. There is a justiciable case or controversy between Plaintiffs and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of Perrigo's Generic Product according to ANDA No. 204255 would infringe one or more claims of the '449 patent.

103. If Defendants' infringement of the '449 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor as follows:

a) United States Patent Nos. 8,435,944; 8,419,307; and 8,177,449 are valid and enforceable;

b) Under 35 U.S.C. § 271(e)(2)(A), Defendants infringed United States Patent Nos. 8,435,944; 8,419,307; and 8,177,449 by submitting ANDA No. 204255 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States Perrigo's Generic Product prior to expiration of said patents;

c) Defendants' threatened acts of commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Perrigo's Generic Product prior to the expiration of United States Patent Nos. 8,435,944; 8,419,307; and 8,177,449 would constitute infringement of said patents;

d) The effective date of any FDA approval of Perrigo's Generic Product shall be no earlier than the latest of the expiration date of United States Patent Nos. 8,435,944; 8,419,307; and 8,177,449 and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

e) Defendants, and all persons acting in concert with Defendants shall be enjoined from commercially manufacturing, using, offering for sale, or selling Perrigo's Generic Product within the United States, or importing Perrigo's Generic Product into the United States, until the expiration of United States Patent Nos. 8,435,944; 8,419,307; and 8,177,449, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

f) This is an exceptional case and Plaintiffs should be awarded their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

g) Plaintiffs are entitled to any further appropriate relief under 35 U.S.C. § 271(e)(4); and

h) Plaintiffs are entitled to any further and additional relief that this Court deems just and proper.

Respectfully submitted,

Dated: May 24, 2013 By: 

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