IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

GALDERMA LABORATORIES, L.P., GALDERMA S.A., and GALDERMA RESEARCH & DEVELOPMENT, S.N.C.,	§	
Plaintiffs,	§	**CIVIL ACTION NO. _____**
v.	§	
PERRIGO ISRAEL PHARMACEUTICALS LTD. and PERRIGO COMPANY,	§	
Defendants.	§	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs GALDERMA LABORATORIES, L.P., GALDERMA S.A., and GALDERMA RESEARCH & DEVELOPMENT, S.N.C. file this Complaint for Patent Infringement against Defendants PERRIGO ISRAEL PHARMACEUTICALS LTD. and PERRIGO COMPANY and state:

PARTIES

1. Galderma Laboratories, L.P. ("Galderma L.P.") is a Texas limited partnership with its principal place of business at 14501 North Freeway, Fort Worth, Texas 76177. Galderma L.P. is the beneficial holder of rights to market Epiduo® (adapalene and benzoyl peroxide) Gel, 0.1% / 2.5% ("Epiduo® Gel") under FDA approval of New Drug Application No. 022320, approved December 8, 2008. Galderma L.P. has the exclusive right from Galderma R&D to distribute Epiduo® Gel in the United States. Epiduo® Gel is a topical gel prescription drug that combines a retinoid (adapalene) and an antimicrobial (benzoyl peroxide) for the treatment of acne vulgaris (severe acne) in people who are at least 12 years old.

2. Galderma S.A. is a Swiss company with its principal place of business at World Trade Center, Avenue de Gratta-Paille 1, Case Postale 552, 1000 Lausanne 30 Grey, Switzerland. Galderma S.A. is involved in the research, development, marketing, and sale of pharmaceutical products.

3. Galderma Research & Development, S.N.C. ("Galderma R&D") is a French corporation with its principal place of business at 2400 Route Des Colles, Les Templiers, Biot, France 06410. Galderma R&D is the current owner of U.S. Patent No. 7,820,186 (the "'186 Patent"), U.S. Patent No. 7,964,202 (the "'202 Patent"), U.S. Patent No. 8,071,644 (the "'644 Patent"), U.S. Patent No. 8,080,537 (the "'537 Patent"), U.S. Patent No. 8,105,618 (the "'618 Patent"), U.S. Patent No. 8,129,362 (the "'362 Patent"), U.S. Patent No. 8,241,649 (the "'649 Patent"), and U.S. Patent No. 8,445,543 (the "'543 Patent") (collectively the "'186, '202, '644, '537, '618, '362, '649, and '543 Patents" or "patents in suit"). A copy of the '186 Patent is attached as Exhibit A. A copy of the '202 Patent is attached as Exhibit B. A copy of the '644 Patent is attached as Exhibit C. A copy of the '537 Patent is attached as Exhibit D. A copy of the '618 Patent is attached as Exhibit E. A copy of the '362 Patent is attached as Exhibit F. A copy of the '649 Patent is attached as Exhibit G. A copy of the '543 Patent is attached as Exhibit H.

4. Perrigo Israel Pharmaceuticals, Ltd. ("Perrigo Israel") is an Israeli corporation with its principal place of business at 29 Lehi Street, Bnei Brak 51200, Israel. On information and belief, Perrigo Israel is a wholly-owned subsidiary of Perrigo Company and is under the direction, control, and/or influence of Perrigo Company, both generally and with respect to the conduct alleged in this Complaint. Perrigo Israel develops, manufactures, markets, and

distributes generic pharmaceutical products for sale in the State of Texas and throughout the United States in concert with its parent company Perrigo Company and related companies.

5. 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 Texas and throughout the United States.

6. Upon information and belief, Perrigo Company is the United States marketing and sales agent for Perrigo Israel, wherein, following FDA approval of an ANDA, Perrigo Israel manufactures and supplies the approved generic drug products to Perrigo Company, which then markets and sells those products throughout the United States, including in this judicial district.

NATURE OF THE ACTION

7. This is a complaint for patent infringement of the ’186, ’202, ’644, ’537, ’618, ’362, ’649, and ’543 Patents. This action relates to ANDA No. 205033 (the “ANDA”) submitted in the name of Perrigo Israel to the U.S. Food and Drug Administration (“FDA”) by its U.S. agent, Perrigo Company, for approval to make, market, and import a generic version of Galderma’s Epiduo® Gel product, which constitutes an act of infringement under the United States Patent Laws, 35 U.S.C. § 100, *et seq.*, including 35 U.S.C. § 271(e)(2).[1]

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of the claims asserted pursuant to 28 U.S.C. §§ 1331 and 1338(a). Venue in this Court is proper under 28 U.S.C. §§ 1391 and 1400(b).

[1] Perrigo Israel and Perrigo Company are sometimes referred to herein collectively as “Perrigo.”

9. Venue is proper in this district because the claims asserted herein arise out of an act of patent infringement (*i.e.*, Defendants' submission of the ANDA and issuance of the Paragraph IV Certification) purposefully targeting a resident of this district (*i.e.*, Galderma L.P.). Further, venue is proper in this district because 21 U.S.C. § 355(j)(5)(C)(i)(II) establishes this district as the only proper venue in which Perrigo could file suit seeking a declaration of non-infringement in connection with the ANDA.

10. The Court has personal jurisdiction over Defendants because they regularly and continuously transact business within the State of Texas. Defendants market and sell pharmaceutical products throughout the United States, including the State of Texas and the Northern District of Texas. Defendants derive substantial revenue from the sale of generic drugs in Texas and have availed themselves of the privilege of conducting business within the State of Texas. Furthermore, Defendants have consented to personal jurisdiction in this venue and availed themselves of the power of this Court in connection with other litigation—including litigation with Galderma. *See, e.g.*, *Galderma Labs., L.P. v. Perrigo Co.*, No. 4:10-cv-00584-Y (N.D. Tex.); *Galderma Labs., L.P. v. Perrigo Co.*, No. 3:09-cv-02322-M (N.D. Tex.); *see also Alcon Pharms., Ltd. v. Perrigo Co.*, No. 4:11-cv-00732-Y-TRM (N.D. Tex.).

11. According to its website, www.perrigo.com, "Perrigo develops, manufactures and distributes over-the-counter (OTC) and generic prescription (Rx) 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. . . ."

12. Perrigo Company's 2013 Annual Report ("Annual Report"), states that it "operates through several wholly owned subsidiaries," including Perrigo Israel. As described in its Annual Report, Perrigo has "four reportable segments that are aligned primarily by type of product: Consumer Healthcare, Nutritionals, Rx Pharmaceuticals and API." The Annual Report explains that "[e]ach of these business segments share Research & Development, 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."

13. The Annual Report also notes that "[t]he Consumer Healthcare segment currently markets over 2,700 store brand products, with over 10,000 stock-keeping units ("SKUs"), to over 1,000 customers." Perrigo Company's Consumer Healthcare segment's "U.S.-based customers are major national and regional retail drug, supermarket and mass merchandise chains, including Walmart, CVS, Walgreens, Kroger, Target, Dollar General, Rite Aid, Sam's Club, Costco, Petco and Petsmart and major wholesalers, including McKesson, Cardinal Health and AmerisourceBergen."

14. Further, the Annual Report also explains that Perrigo Company's "Rx Pharmaceuticals segment develops, manufactures and markets a portfolio of generic prescription drugs primarily 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, ophthalmics, suppositories, sprays, liquids, suspensions, solutions and powders." The Annual Report explains that the Rx Pharmaceuticals segment "develops, manufactures and markets primarily generic 'extended topical' and other specialty prescription pharmaceuticals. Topical and specialty products are manufactured at the

Company's New York, Minnesota, Israel and U.K. facilities and are also sourced from various FDA-approved third parties."

15. According to the Annual Report, the Rx Pharmaceuticals segment "currently markets approximately 700 generic prescription and ORx® products, with almost 1,400 SKUs, to approximately 300 customers" and that Perrigo "generally holds the ANDA or product application for the drugs that it manufactures or enters into an arrangement with the application holder for the manufacture and/or marketing of certain products." Additionally, the Annual Report explains that for the Rx Pharmaceuticals segment, its "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, Walmart, CVS, Rite Aid, Kroger and Safeway" and that "[g]eneric prescription drugs are sold to the consumer through the pharmacy counter of predominantly the same retail outlets as OTC pharmaceuticals and nutritional products."

16. Upon information and belief, Perrigo Company acted in concert with Perrigo Israel to develop and to seek approval from the FDA to sell the Accused Product throughout the United States, Texas, and this judicial district. Indeed, Perrigo Company is listed as Perrigo Israel's authorized U.S. agent and submitted the ANDA on behalf of Perrigo Israel. On information and belief, Perrigo Company participated in the preparation and submission of the ANDA and will benefit directly and indirectly upon the approval of the ANDA.

BACKGROUND FACTS

A. The '186 Patent

17. On October 26, 2010, the United States Patent and Trademark Office ("USPTO") issued the '186 Patent, entitled "Gel Composition for Once-Daily Treatment of Common Acne

Comprising a Combination of Benzoyl Peroxide and Adapalene and/or Adapalene Salt," to Galderma R&D.

18. The '186 Patent is valid, enforceable, and has not expired.

B. The '202 Patent

19. On June 21, 2011, the USPTO issued the '202 Patent, entitled "Method for Treatment of Common Acne," to Galderma R&D.

20. The '202 Patent is valid, enforceable, and has not expired.

C. The '644 Patent

21. On December 6, 2011, the USPTO issued the '644 Patent, entitled "Combinations of Adapalene and Benzoyl Peroxide for Treating Acne Lesions," to Galderma R&D.

22. The '644 Patent is valid, enforceable, and has not expired.

D. The '537 Patent

23. On December 20, 2011, the USPTO issued the '537 Patent, entitled "Combinations of Adapalene and Benzoyl Peroxide for Treating Acne Lesions," to Galderma R&D.

24. The '537 Patent is valid, enforceable, and has not expired.

E. The '618 Patent

25. On January 31, 2012, the USPTO issued the '618 Patent, entitled "Dermatological/Cosmetic Gels Comprising At Least One Retinoid and/or Retinoid Salt and Benzoyl Peroxide," to Galderma R&D.

26. The '618 Patent is valid, enforceable, and has not expired.

F. The ’362 Patent

27. On March 6, 2012, the USPTO issued the ’362 Patent, entitled “Combination/ Association of Adapalene and Benzoyl Peroxide for Treating Acne Lesions,” to Galderma R&D.

28. The ’362 Patent is valid, enforceable, and has not expired.

G. The ’649 Patent

29. On August 14, 2012, the USPTO issued the ’649 Patent, entitled “Dermatological/Cosmetic Gels Comprising at Least One Retinoid and/or Retinoid Salt and Benzoyl Peroxide,” to Galderma R&D.

30. The ’649 Patent is valid, enforceable, and has not expired.

H. The ’543 Patent

31. On May 21, 2013, the USPTO issued the ’543 Patent, entitled “Combinations of Adapalene and Benzoyl Peroxide for Treating Acne Lesions,” to Galderma R&D.

32. The ’543 Patent is valid, enforceable, and has not expired.

G. Epiduo® Gel

33. Galderma L.P. is the holder of New Drug Application (“NDA”) No. 022320. On December 8, 2008, Galderma L.P. obtained FDA Approval to market Epiduo® Gel. The ’186, ’202, ’644, ’537, ’618, ’362, ’649, and ’543 Patents are listed in the FDA publication titled *Approved Drug Products With Therapeutic Equivalence Evaluations* (known as the “Orange Book”) as covering Epiduo® (adapalene and benzoyl peroxide) Gel, 0.1% / 2.5%.

34. Galderma S.A. and Galderma R&D have granted Galderma L.P. the exclusive right under the Orange Book patents to distribute Epiduo® Gel in the United States.

I. Perrigo's Infringement

35. Perrigo is in the business of developing, manufacturing, marketing, selling, and importing generic pharmaceutical products.

36. On or about December 12, 2012, Perrigo filed or caused to be filed with the FDA ANDA No. 205033, which seeks approval to engage in the commercial manufacture, use, sale, or importation of generic adapalene and benzoyl peroxide gel, 0.1% / 2.5% ("the Accused Product") prior to the expiration of the '186, '202, '644, '537, '618, '362, '649, and '543 Patents.

37. Perrigo Company and Perrigo Israel acted in concert to prepare and submit the ANDA.

38. As part of its ANDA, Perrigo included a sample of the label and package insert it intends to use for the Accused Product, which is substantially identical to Epiduo®'s label and package insert. Epiduo®'s label and package insert inform users that the usual dosage is to apply a thin film once a day to affected areas.

39. Perrigo's labeling shows that its generic product will be manufactured in Israel and distributed by Perrigo, Allegan, Michigan. Additionally, the labeling provides the web address for Perrigo Company's website, www.perrigo.com.

40. The Accused Product that is the subject of the ANDA directly and indirectly infringes one or more claims of the '186, '202, '644, '537, '618, '362, '649, and '543 Patents either literally or under the doctrine of equivalents.

41. On or about August 14, 2013, Perrigo sent or caused to be sent a letter (the "Certification Letter") to Galderma L.P. in Fort Worth, Texas, Galderma R&D in France, and Galderma S.A. in Switzerland. Through the Certification Letter, Perrigo first notified Plaintiffs

that it had filed the ANDA with the FDA relating to the Accused Product and that the ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that, in Perrigo's opinion, the claims of the '186, '202, '644, '537, '618, '362, '649, and '543 Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, or importation of the Accused Product.

42. Perrigo was aware of the '186, '202, '644, '537, '618, '362, '649, and '543 Patents when it filed the ANDA and/or sent the Certification Letter. On information and belief, Perrigo also reviewed the '186, '202, '644, '537, '618, '362, '649, and '543 Patents and certain commercial and economic information relating to Epiduo® Gel, including estimates of the revenues generated by the sale of Epiduo® Gel.

43. Perrigo's submission of the ANDA to the FDA constitutes infringement by Perrigo of the '186, '202, '644, '537, '618, '362, '649, and '543 Patents under 35 U.S.C. §271(e)(2). Moreover, any commercial manufacture, use, sale, offer for sale, or importation of Perrigo's Accused Product prior to the expiration of the patents in suit would infringe the '186, '202, '644, '537, '618, '362, '649, and '543 Patents under 35 U.S.C. §271(a), (b), and/or (g).

44. Upon approval of the ANDA, Perrigo will infringe the patents in suit, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Accused Product in the United States, and by actively inducing others. By way of example, and based on information and belief, the Accused Product when offered for sale, sold and/or imported, and when used as directed, would be used in a manner that would directly infringe (either literally or under the doctrine of equivalents) at least one claim of each of the patents in suit. Indeed, based on information and belief, Perrigo knows and intends that

physicians will prescribe and patients will use the Accused Product for which approval is sought in the ANDA as described by the Accused Product's labeling.

45. On information and belief, Perrigo plans to make, use, sell, offer to sell, and/or import the Accused Product (including within the State of Texas and this District) for uses that will infringe the patents in suit in the event the FDA approves the ANDA.

46. Plaintiffs will be substantially and irreparably harmed by Perrigo's infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

47. Plaintiffs have commenced this action within 45 days of the date that they received Perrigo's notice of the ANDA containing the Paragraph IV certification.

COUNT I:
INFRINGEMENT OF U.S. PATENT NO. 7,820,186

48. Plaintiffs incorporate paragraphs 1 through 47 above by reference as if fully set forth herein.

49. The '186 Patent is valid, enforceable, and has not expired.

50. The Accused Product and/or its use as directed infringes one or more of the claims of the '186 Patent, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Perrigo infringed the '186 Patent by submitting the ANDA seeking permission to commercially manufacture, use, sell, or import the Accused Product prior to the expiration of the '186 Patent.

51. Upon FDA approval of the ANDA, Perrigo will infringe the '186 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing the Accused Product.

52. As a result of Perrigo's infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the '186 Patent if made, used as directed, sold, offered for sale, or imported during the term of the '186 Patent.

53. As a result of Perrigo's infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Perrigo and all those in privity with or acting in concert with Perrigo from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the '186 Patent, or from otherwise infringing or inducing the infringement of the '186 Patent.

COUNT II:
INFRINGEMENT OF U.S. PATENT NO. 7,964,202

54. Plaintiffs incorporate paragraphs 1 through 53 above by reference as if fully set forth herein.

55. The '202 Patent is valid, enforceable, and has not expired.

56. The Accused Product and/or its use as directed infringes one or more of the claims of the '202 Patent, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Perrigo infringed the '202 Patent by submitting the ANDA seeking permission to commercially manufacture, use, sell, or import the Accused Product prior to the expiration of the '202 Patent.

57. Upon information and belief, Perrigo will induce infringement of one or more claims of the '202 Patent—in violation of Plaintiffs' patent rights—if the FDA approves the sale of the Accused Product with instructions and labeling that will result in direct infringement of one or more claims of the '202 Patent by users of the Accused Product.

58. On information and belief, Perrigo seeks approval of at least one indication for the Accused Product that is claimed in the '202 Patent.

59. On information and belief, Perrigo has knowledge of the ’202 Patent and by their promotional activities, package insert, and labeling will know or should know that physicians will prescribe, and patients will use, the Accused Product in accordance with the indication(s) sought by Perrigo and will therefore infringe one or more claims of the ’202 Patent under 35 U.S.C. § 271(b).

60. As a result of Perrigo’s infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the ’202 Patent if made, used as directed, sold, offered for sale, or imported during the term of the ’202 Patent.

61. As a result of Perrigo’s infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Perrigo and all those in privity with or acting in concert with Perrigo from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the ’202 Patent, or from otherwise infringing or inducing the infringement of the ’202 Patent.

COUNT III:
INFRINGEMENT OF U.S. PATENT NO. 8,071,644

62. Plaintiffs incorporate paragraphs 1 through 61 above by reference as if fully set forth herein.

63. The ’644 Patent is valid, enforceable, and has not expired.

64. The Accused Product and/or its use as directed infringes one or more of the claims of the ’644 Patent, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Perrigo infringed the ’644 Patent by submitting the ANDA seeking permission to commercially manufacture, use, sell, or import the Accused Product prior to the expiration of the ’644 Patent.

65. Upon information and belief, Perrigo will induce infringement of one or more claims of the ’644 Patent—in violation of Plaintiffs’ patent rights—if the FDA approves the sale of the Accused Product with instructions and labeling that will result in direct infringement of one or more claims of the ’644 Patent by users of the Accused Product.

66. On information and belief, Perrigo seeks approval of at least one indication for the Accused Product that is claimed in the ’644 Patent.

67. On information and belief, Perrigo has knowledge of the ’644 Patent and by their promotional activities, package insert, and labeling will know or should know that physicians will prescribe, and patients will use, the Accused Product in accordance with the indication(s) sought by Perrigo and will therefore infringe one or more claims of the ’644 Patent under 35 U.S.C. § 271(b).

68. As a result of Perrigo’s infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the ’644 Patent if made, used as directed, sold, offered for sale, or imported during the term of the ’644 Patent.

69. As a result of Perrigo’s infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Perrigo and all those in privity with or acting in concert with Perrigo from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the ’644 Patent, or from otherwise infringing or inducing the infringement of the ’644 Patent.

COUNT IV:
INFRINGEMENT OF U.S. PATENT NO. 8,080,537

70. Plaintiffs incorporate paragraphs 1 through 69 above by reference as if fully set forth herein.

71. The ’537 Patent is valid, enforceable, and has not expired.

72. The Accused Product and/or its use as directed infringes one or more of the claims of the ’537 Patent, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Perrigo infringed the ’537 Patent by submitting the ANDA seeking permission to commercially manufacture, use, sell, or import the Accused Product prior to the expiration of the ’537 Patent.

73. Upon information and belief, Perrigo will induce infringement of one or more claims of the ’537 Patent—in violation of Plaintiffs’ patent rights—if the FDA approves the sale of the Accused Product with instructions and labeling that will result in direct infringement of one or more claims of the ’537 Patent by users of the Accused Product.

74. On information and belief, Perrigo seeks approval of at least one indication for the Accused Product that is claimed in the ’537 Patent.

75. On information and belief, Perrigo has knowledge of the ’537 Patent and by their promotional activities, package insert, and labeling will know or should know that physicians will prescribe, and patients will use, the Accused Product in accordance with the indication(s) sought by Perrigo and will therefore infringe one or more claims of the ’537 Patent under 35 U.S.C. § 271(b).

76. As a result of Perrigo’s infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the ’537 Patent if made, used as directed, sold, offered for sale, or imported during the term of the ’537 Patent.

77. As a result of Perrigo’s infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Perrigo and all those in privity with or acting in concert with Perrigo from manufacturing, selling, offering to sell, or importing the Accused

Product during the term of the ’537 Patent, or from otherwise infringing or inducing the infringement of the ’537 Patent.

COUNT V:
INFRINGEMENT OF U.S. PATENT NO. 8,105,618

78. Plaintiffs incorporate paragraphs 1 through 77 above by reference as if fully set forth herein.

79. The ’618 Patent is valid, enforceable, and has not expired.

80. The Accused Product and/or its use as directed infringes one or more of the claims of the ’618 Patent, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Perrigo infringed the ’618 Patent by submitting the ANDA seeking permission to commercially manufacture, use, sell, or import the Accused Product prior to the expiration of the ’618 Patent.

81. Upon information and belief, Perrigo will induce infringement of one or more claims of the ’618 Patent—in violation of Plaintiffs’ patent rights—if the FDA approves the sale of the Accused Product with instructions and labeling that will result in direct infringement of one or more claims of the ’618 Patent by users of the Accused Product.

82. On information and belief, Perrigo seeks approval of at least one indication for the Accused Product that is claimed in the ’618 Patent.

83. On information and belief, Perrigo has knowledge of the ’618 Patent and by their promotional activities, package insert, and labeling will know or should know that physicians will prescribe, and patients will use, the Accused Product in accordance with the indication(s) sought by Perrigo and will therefore infringe one or more claims of the ’618 Patent under 35 U.S.C. § 271(b).

84. As a result of Perrigo's infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the '618 Patent if made, used as directed, sold, offered for sale, or imported during the term of the '618 Patent.

85. As a result of Perrigo's infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Perrigo and all those in privity with or acting in concert with Perrigo from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the '618 Patent, or from otherwise infringing or inducing the infringement of the '618 Patent.

COUNT VI:
INFRINGEMENT OF U.S. PATENT NO. 8,129,362

86. Plaintiffs incorporate paragraphs 1 through 85 above by reference as if fully set forth herein.

87. The '362 Patent is valid, enforceable, and has not expired.

88. The Accused Product and/or its use as directed infringes one or more of the claims of the '362 Patent, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Perrigo infringed the '362 Patent by submitting the ANDA seeking permission to commercially manufacture, use, sell, or import the Accused Product prior to the expiration of the '362 Patent.

89. Upon information and belief, Perrigo will induce infringement of one or more claims of the '362 Patent—in violation of Plaintiffs' patent rights—if the FDA approves the sale of the Accused Product with instructions and labeling that will result in direct infringement of one or more claims of the '362 Patent by users of the Accused Product.

90. On information and belief, Perrigo seeks approval of at least one indication for the Accused Product that is claimed in the '362 Patent.

91. On information and belief, Perrigo has knowledge of the ’362 Patent and by their promotional activities, package insert, and labeling will know or should know that physicians will prescribe, and patients will use, the Accused Product in accordance with the indication(s) sought by Perrigo and will therefore infringe one or more claims of the ’362 Patent under 35 U.S.C. § 271(b).

92. As a result of Perrigo’s infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the ’362 Patent if made, used as directed, sold, offered for sale, or imported during the term of the ’362 Patent.

93. As a result of Perrigo’s infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Perrigo and all those in privity with or acting in concert with Perrigo from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the ’362 Patent, or from otherwise infringing or inducing the infringement of the ’362 Patent.

COUNT VII:
INFRINGEMENT OF U.S. PATENT NO. 8,241,649

94. Plaintiffs incorporate paragraphs 1 through 93 above by reference as if fully set forth herein.

95. The ’649 Patent is valid, enforceable, and has not expired.

96. The Accused Product and/or its use as directed infringes one or more of the claims of the ’649 Patent, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Perrigo infringed the ’649 Patent by submitting and/or amending the ANDA seeking permission to commercially manufacture, use, sell, or import the Accused Product prior to the expiration of the ’649 Patent.

97. As a result of Perrigo's infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the '649 Patent if made, used as directed, sold, offered for sale, or imported during the term of the '649 Patent.

98. As a result of Perrigo's infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Perrigo and all those in privity with or acting in concert with Perrigo from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the '649 Patent, or from otherwise infringing or inducing the infringement of the '649 Patent.

COUNT VIII:
INFRINGEMENT OF U.S. PATENT NO. 8,445,543

99. Plaintiffs incorporate paragraphs 1 through 98 above by reference as if fully set forth herein.

100. The '543 Patent is valid, enforceable, and has not expired.

101. The Accused Product and/or its use as directed infringes one or more of the claims of the '543 Patent, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Perrigo infringed the '543 Patent by submitting the ANDA seeking permission to commercially manufacture, use, sell, or import the Accused Product prior to the expiration of the '543 Patent.

102. Upon information and belief, Perrigo will induce infringement of one or more claims of the '543 Patent—in violation of Plaintiffs' patent rights—if the FDA approves the sale of the Accused Product with instructions and labeling that will result in direct infringement of one or more claims of the '543 Patent by users of the Accused Product.

103. On information and belief, Perrigo seeks approval of at least one indication for the Accused Product that is claimed in the '543 Patent.

104. On information and belief, Perrigo has knowledge of the ’543 Patent and by their promotional activities, package insert, and labeling will know or should know that physicians will prescribe, and patients will use, the Accused Product in accordance with the indication(s) sought by Perrigo and will therefore infringe one or more claims of the ’543 Patent under 35 U.S.C. § 271(b).

105. Plaintiffs will be substantially and irreparably harmed by Perrigo’s infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

106. As a result of Perrigo’s infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the ’543 Patent if made, used as directed, sold, offered for sale, or imported during the term of the ’543 Patent.

107. As a result of Perrigo’s infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Perrigo and all those in privity with or acting in concert with Perrigo from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the ’543 Patent, or from otherwise infringing or inducing the infringement of the ’543 Patent.

DEMAND FOR JURY TRIAL

In the event Perrigo commercially manufactures, uses, sells, offers to sell, or imports the Accused Product prior to trial, Plaintiffs demand trial by jury of all issues and claims alleged herein.

PRAYER FOR RELIEF

WHEREFORE Plaintiffs pray for the following relief:

(A) A declaration that Perrigo's commercial manufacture, use, offer for sale, or sale in, or importation into the United States of the Accused Product prior to the date of the expiration of the '186, '202, '644, '537, '618, '362, '649, and '543 Patents, including any patent extensions and any additional periods of exclusivity, would constitute infringement of such patents in violation of Plaintiffs' patent rights;

(B) A declaration, pursuant to 35 U.S.C. § 271(e)(2)(A), that Perrigo has infringed the '186, '202, '644, '537, '618, '362, '649, and '543 Patents by submitting the ANDA to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell in, or import into the United States the Accused Product prior to the expiration of such patents, including any patent extensions and any additional periods of exclusivity, and that the Accused Product infringes such patents;

(C) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of the Accused Product described in the ANDA is not to be earlier than the date of the expiration of the'186, '202, '644, '537, '618, '362, '649, and '543 Patents, including any patent extensions and any additional periods of exclusivity;

(D) A permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and (D) and 35 U.S.C. § 283, enjoining Perrigo and their officers, agents, servants, employees, privies, and others acting for, on behalf of, or in concert with any of them, from commercially manufacturing, using, selling, or offering to sell the Accused Product within the United States; importing the Accused Product into the United States; or otherwise infringing or inducing the infringement of the '186, '202, '644, '537, '618, '362, '649, and '543 Patents prior to the date of

the expiration of such patents, including any patent extensions and any additional periods of exclusivity;

(E) An award to Plaintiffs, pursuant to 35 U.S.C. § 271(e)(4)(C), of damages and other monetary relief, as a result of Perrigo's infringement, to the extent there has been any commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the Accused Product prior to the date of the expiration of the '186, '202, '644, '537, '618, '362, '649, and '543 Patents, including any patent extensions and any additional periods of exclusivity; and

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

Respectfully submitted,

/s/ *Jamil N. Alibhai*

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