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

GALDERMA LABORATORIES, L.P., GALDERMA S.A., and NESTLÉ SKIN HEALTH S.A.,	§	
Plaintiffs,	§	
v.	§	**CIVIL ACTION NO. _____**
PERRIGO UK FINCO LIMITED PARTNERSHIP and PERRIGO ISRAEL PHARMACEUTICALS LTD.,	§	
Defendants.	§	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs GALDERMA LABORATORIES, L.P., GALDERMA S.A., and NESTLÉ SKIN HEALTH S.A. (collectively, "Galderma" or "Plaintiffs") file this Complaint for patent infringement against Defendants PERRIGO UK FINCO LIMITED PARTNERSHIP and PERRIGO ISRAEL PHARMACEUTICALS LTD. (collectively, "Perrigo" or "Defendants") as follows:

PARTIES

1. Galderma Laboratories, L.P. ("GLP") is a Texas limited partnership with its principal place of business at 14501 North Freeway, Fort Worth, Texas 76177. GLP holds the exclusive right to use, manufacture, and sell Galderma's patented products in the United States, including Soolantra® (ivermectin) Cream 1%, under FDA approval of New Drug Application ("NDA") No. 206255, approved December 19, 2014. Moreover, GLP is responsible for seeking regulatory approvals of Galderma's products in the United States, and is the sole owner of NDA No. 206255.

2. Galderma S.A. ("GSA") is a Swiss company with its principal place of business at Avenue Gratta-Paille 2, CH-1018 Lausanne, Switzerland.

3. Nestlé Skin Health S.A. (Nestlé) is a Swiss company with its principal place of business at Avenue Gratta-Paille 2, CH-1018 Lausanne, Switzerland.

4. Galderma owns U.S. Patent No. 8,815,816 (the "'816 Patent"), U.S. Patent No. 9,089,587 (the "'587 Patent"), U.S. Patent No. 9,233,117 (the "'117 Patent"), and U.S. Patent No. 9,233,118 (the "'118 Patent") (collectively, the "Asserted Patents"). A copy of the '816 Patent is attached as Exhibit "A." A copy of the '587 Patent is attached as Exhibit "B." A copy of the '117 Patent is attached as Exhibit "C." A copy of the '118 Patent is attached as Exhibit "D."

5. Soolantra® (ivermectin) Cream, 1% is indicated for the treatment of inflammatory lesions of rosacea.

6. Perrigo UK Finco Limited Partnership ("Perrigo UK") is organized and exists under the laws of the United Kingdom, with its principal place of business at Wrafton, Braunton, Devon, EX33 2DL, United Kingdom.

7. Perrigo Israel Pharmaceuticals Ltd. ("Perrigo Israel") is an Israeli company with its principal place of business at 29 Lehi Street Bnei Brak, 5120 Israel.

JURISDICTION AND VENUE

8. This is a complaint for patent infringement. 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(c)(3) and 1400(b).

9. This Court has personal jurisdiction over Perrigo because it files Abbreviated New Drug Applications ("ANDAs"), including the ANDA at issue here, for the purpose of

collectively manufacturing, importing, offering for sale, selling, and/or distributing generic pharmaceutical products throughout the United States, including this judicial district. Perrigo markets and sells 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, Perrigo Israel has consented to personal jurisdiction in this venue, filed counterclaims, and availed itself 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. et al.*, No. 4:10-cv-00584-Y (N.D. Tex.); *Galderma Labs., L.P. v. Perrigo Co. et al.*, No. 3:09-cv-02322-M (N.D. Tex.); *see also Alcon Pharms., Ltd. v. Perrigo Co. et al*, No. 4:11-cv-00732-Y-TRM (N.D. Tex.).

10. Perrigo UK submitted the ANDA (an act of infringement under 35 U.S.C. § 271(e)(2)) for the infringing product and issued a certification under 21 U.S.C. § 355(j)(2)(B) (the "Paragraph IV Certification")—the acts which give rise to the instant litigation—with knowledge that GLP—a company located in this district—would be injured by such actions in this district, and delivered its Paragraph IV Certification to GLP in this district. Perrigo intends to sell the infringing product in or for distribution in this district upon approval by the FDA. Perrigo has thus purposefully targeted its conduct to cause harm in the State of Texas, and particularly in this district.

11. Venue is proper in this district because the claims asserted herein arise out of an act of patent infringement—Perrigo's submission of the ANDA and issuance of the Paragraph IV Certification—purposefully targeting a resident of this district, GLP. 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 for seeking a declaration of non-infringement or invalidity in connection with the ANDA.

BACKGROUND FACTS

A. The '816 Patent

12. On August 26, 2014, the USPTO issued the '816 Patent, entitled "Topical Application of Ivermectin for the Treatment of Dermatological Conditions/Afflictions," to GSA.

13. The '816 Patent is valid, enforceable, and has not expired.

B. The '587 Patent

14. On July 28, 2015, the USPTO issued the '587 Patent, entitled "Treatment of Papulopustular Rosacea With Ivermectin," to GSA.

15. The '587 Patent is valid, enforceable, and has not expired.

C. The '117 Patent

16. On January 12, 2016, the USPTO issued the '117 Patent, entitled "Treatment of Inflammatory Lesions of Rosacea With Ivermectin," to GSA.

17. The '117 Patent is valid, enforceable, and has not expired.

D. The '118 Patent

18. On January 12, 2016, the USPTO issued the '118 Patent, entitled "Treatment of Papulopustular Rosacea With Ivermectin," to GSA.

19. The '118 Patent is valid, enforceable, and has not expired.

E. Soolantra® (Ivermectin) Cream, 1%

20. GLP is the exclusive owner of NDA No. 206255, giving it sole permission to market and sell Soolantra® (ivermectin) Cream, 1% in the United States. On December 19, 2014, GLP obtained FDA approval to market Soolantra® (ivermectin) Cream, 1%. The '816

Patent, ˈ587 Patent, ˈ117 Patent, and ˈ118 Patent are listed in the FDA publication entitled, "Approved Drug Products With Therapeutic Equivalence Evaluations" (known as the "Orange Book") as covering Soolantra® (ivermectin) Cream, 1%.

F. Perrigoˈs Infringement

21. Perrigo UK and Perrigo Israel are involved in the development, manufacturing, regulatory approval, importing, marketing, sale, and distribution of pharmaceutical products, including the product described in ANDA No. 210225.

22. On March 30, 2017, Perrigo UK filed an application seeking FDA approval to sell a generic version of Soolantra® (ivermectin) Cream, 1%.

23. During the process of preparing such application, Perrigo reviewed at least the ˈ816 Patent, ˈ587 Patent, ˈ117 Patent, and ˈ118 Patent and certain commercial and economic information relating to Soolantra® (ivermectin) Cream, 1%.

24. Perrigo UK submitted ANDA No. 210225 seeking approval to engage in the commercial manufacture, use, and sale of generic ivermectin cream, 1% (the "Accused Product" or "Infringing Product") prior to the expiration of the Asserted Patents.

25. The Accused Product that is the subject of the ANDA will directly and indirectly infringe one or more claims of the Asserted Patents, either literally or under the doctrine of equivalents.

26. On or about June 1, 2017, Perrigo UK sent the Paragraph IV Certification to GLP in Fort Worth, Texas and to GSA. Through the Paragraph IV Certification, Perrigo UK first notified Plaintiffs that Perrigo UK 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) that, in Perrigo UKˈs opinion, the claims of the ˈ816 Patent, ˈ587 Patent, ˈ117 Patent, and ˈ118 Patent

are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, or importation of the Accused Product.

27. Perrigo was aware of at least the ʹ816 Patent, ʹ587 Patent, ʹ117 Patent, and ʹ118 Patent when it filed the ANDA and/or sent the Paragraph IV Certification.

28. Plaintiffs have commenced this action within 45 days of the date that they received the Paragraph IV Certification.

29. Perrigo intends to continue seeking approval of the ANDA from the FDA, and to engage in the commercial manufacture, marketing, and sale of the Accused Product (including commercial marketing and sale of the Accused Product in the State of Texas and this District), in the event that the FDA approves the ANDA.

COUNT I:
INFRINGEMENT OF U.S. PATENT NO. 8,815,816

30. Plaintiffs incorporate paragraphs 1 through 29 above by reference as if fully set forth herein.

31. The ʹ816 Patent is valid, enforceable, and has not expired.

32. The Accused Product and/or its use as directed infringes one or more of the claims of the ʹ816 Patent, including at least claim 1, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Perrigo infringed the ʹ816 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the ʹ816 Patent.

33. Perrigo will induce infringement of one or more claims of the ʹ816 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, including at least claim 1, of the ʹ816 Patent by users of the Accused Product.

34. Perrigo seeks approval of at least one indication for the Accused Product that is claimed in the '816 Patent.

35. Perrigo intends 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 '816 Patent under 35 U.S.C. § 271(b).

36. In addition, pursuant to the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355 *et seq.*, Perrigo's ANDA must include information showing that the Accused Product (1) contains the same active ingredients as Soolantra® (ivermectin) Cream, 1% [21 U.S.C. § 355(j)(2)(A)(II)]; (2) has the same route of administration, dosage form, and strength as Soolantra® (ivermectin) Cream, 1% [21 U.S.C. § 355(j)(2)(A)(iii)]; and (3) is bioequivalent and/or has the same therapeutic effect as Soolantra® (ivermectin) Cream, 1% [21 U.S.C. § 355(j)(2)(A)(iv)].

37. As such, under 35 U.S.C. § 271(e)(2)(A), Perrigo has infringed the '816 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '816 Patent.

38. As a result of Perrigo's infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the '816 Patent if made, used as directed, sold, offered for sale, or imported during the term of the '816 Patent.

39. 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.

40. As a result of Perrigo's infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Perrigo and all those in privity or acting in concert

with Perrigo from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the ʹ816 Patent, or from otherwise infringing or inducing the infringement of the ʹ816 Patent.

COUNT II:
INFRINGEMENT OF U.S. PATENT NO. 9,089,587

41. Plaintiffs incorporate paragraphs 1 through 40 above by reference as if fully set forth herein.

42. The ʹ587 Patent is valid, enforceable, and has not expired.

43. The Accused Product and/or its use as directed infringes one or more of the claims of the ʹ587 Patent, including at least claim 1, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Perrigo infringed the ʹ587 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the ʹ587 Patent.

44. Perrigo will induce infringement of one or more claims of the ʹ587 Patent—in violation of Plaintiffsʹ 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, including at least claim 1, of the ʹ587 Patent by users of the Accused Product.

45. Perrigo seeks approval of at least one indication for the Accused Product that is claimed in the ʹ587 Patent.

46. Perrigo intends 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 ʹ587 Patent under 35 U.S.C. § 271(b).

47. In addition, pursuant to the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355 *et seq.*, Perrigoʹs ANDA must include information showing that the

Accused Product (1) contains the same active ingredients as Soolantra® (ivermectin) Cream, 1% [21 U.S.C. § 355(j)(2)(A)(II)]; (2) has the same route of administration, dosage form, and strength as Soolantra® (ivermectin) Cream, 1% [21 U.S.C. § 355(j)(2)(A)(iii)]; and (3) is bioequivalent and/or has the same therapeutic effect as Soolantra® (ivermectin) Cream, 1% [21 U.S.C. § 355(j)(2)(A)(iv)].

48. As such, under 35 U.S.C. § 271(e)(2)(A), Perrigo has infringed the ʹ587 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the ʹ587 Patent.

49. As a result of Perrigoʹs infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the ʹ587 Patent if made, used as directed, sold, offered for sale, or imported during the term of the ʹ587 Patent.

50. Plaintiffs will be substantially and irreparably harmed by Perrigoʹs infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

51. As a result of Perrigoʹs infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Perrigo and all those in privity or acting in concert with Perrigo from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the ʹ587 Patent, or from otherwise infringing or inducing the infringement of the ʹ587 Patent.

COUNT III:
INFRINGEMENT OF U.S. PATENT NO. 9,233,117

52. Plaintiffs incorporate paragraphs 1 through 51 above by reference as if fully set forth herein.

53. The ʹ117 Patent is valid, enforceable, and has not expired.

54. The Accused Product and/or its use as directed infringes one or more of the claims of the '117 Patent, including at least claim 1, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Perrigo infringed the '117 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '117 Patent.

55. Perrigo will induce infringement of one or more claims of the '117 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, including at least claim 1, of the '117 Patent by users of the Accused Product.

56. Perrigo seeks approval of at least one indication for the Accused Product that is claimed in the '117 Patent.

57. Perrigo intends 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 '117 Patent under 35 U.S.C. § 271(b).

58. In addition, pursuant to the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355 *et seq.*, Perrigo's ANDA must include information showing that the Accused Product (1) contains the same active ingredients as Soolantra® (ivermectin) Cream, 1% [21 U.S.C. § 355(j)(2)(A)(II)]; (2) has the same route of administration, dosage form, and strength as Soolantra® (ivermectin) Cream, 1% [21 U.S.C. § 355(j)(2)(A)(iii)]; and (3) is bioequivalent and/or has the same therapeutic effect as Soolantra® (ivermectin) Cream, 1% [21 U.S.C. § 355(j)(2)(A)(iv)].

59. As such, under 35 U.S.C. § 271(e)(2)(A), Perrigo has infringed the ʹ117 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the ʹ117 Patent.

60. As a result of Perrigoʹs infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the ʹ117 Patent if made, used as directed, sold, offered for sale, or imported during the term of the ʹ117 Patent.

61. Plaintiffs will be substantially and irreparably harmed by Perrigoʹs infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

62. As a result of Perrigoʹs infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Perrigo and all those in privity or acting in concert with Perrigo from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the ʹ117 Patent, or from otherwise infringing or inducing the infringement of the ʹ117 Patent.

COUNT IV:
INFRINGEMENT OF U.S. PATENT NO. 9,233,118

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

64. The ʹ118 Patent is valid, enforceable, and has not expired.

65. The Accused Product and/or its use as directed infringes one or more of the claims of the ʹ118 Patent, including at least claim 1, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Perrigo infringed the ʹ118 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the ʹ118 Patent.

66. Perrigo will induce infringement of one or more claims of the '118 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, including at least claim 1, of the '118 Patent by users of the Accused Product.

67. Perrigo seeks approval of at least one indication for the Accused Product that is claimed in the '118 Patent.

68. Perrigo intends 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 '118 Patent under 35 U.S.C. § 271(b).

69. In addition, pursuant to the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355 *et seq.*, Perrigo's ANDA must include information showing that the Accused Product (1) contains the same active ingredients as Soolantra® (ivermectin) Cream, 1% [21 U.S.C. § 355(j)(2)(A)(II)]; (2) has the same route of administration, dosage form, and strength as Soolantra® (ivermectin) Cream, 1% [21 U.S.C. § 355(j)(2)(A)(iii)]; and (3) is bioequivalent and/or has the same therapeutic effect as Soolantra® (ivermectin) Cream, 1% [21 U.S.C. § 355(j)(2)(A)(iv)].

70. As such, under 35 U.S.C. § 271(e)(2)(A), Perrigo has infringed the '118 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '118 Patent.

71. As a result of Perrigo's infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the '118 Patent if made, used as directed, sold, offered for sale, or imported during the term of the '118 Patent.

72. 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.

73. As a result of Perrigo's infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Perrigo and all those in privity or acting in concert with Perrigo from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the '118 Patent, or from otherwise infringing or inducing the infringement of the '118 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 Asserted 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 Asserted 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 Asserted 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 its 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 Asserted 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 Asserted 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.

Dated: July 13, 2017

Respectfully submitted,

/s/ Jamil N. Alibhai

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