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. _____**
ACTAVIS LABORATORIES UT, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES 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 ACTAVIS LABORATORIES UT, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD. (collectively, "Teva" 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. 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. 8,362,069 (the "'069 Patent"), 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 '069 Patent is attached as "A." A copy of the '816 Patent is attached as Exhibit "B." A copy of the '587 Patent is attached as Exhibit "C." A copy of the '117 Patent is attached as Exhibit "D." A copy of the '118 Patent is attached as Exhibit "E."

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

6. Actavis Laboratories UT, Inc. ("Actavis UT") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 577 Chipeta Way, Salt Lake City, Utah 84108. Actavis UT may be served with process by and through its registered agent for service of process, Corporate Creations Network Inc., at 3411 Silverside Road #104 Tatnall Building, Wilmington, Delaware 19810. Actavis UT is an indirect wholly-owned subsidiary of Teva Pharmaceuticals USA, Inc. ("Teva USA") and acts at the direction of, under the control of, and for the benefit of Teva USA.

7. Teva USA is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, North Wales,

Pennsylvania 19454. Teva USA may be served with process by and through its registered agent for service of process, Corporate Creations Network Inc., at 3411 Silverside Road #104 Tatnall Building, Wilmington, Delaware 19810. Teva USA is a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd. ("Teva Israel"), and acts at the direction of, under the control of, and for the benefit of Teva Israel.

8. Teva Israel is an Israeli company with its principal place of business at 5 Basel Street, Petach Tikva, 4951033, Israel. On August 2, 2016, Teva Israel purchased Allergan plc's generic pharmaceuticals business, including Actavis UT. Teva Israel may be served with process by and through its agent in the United States, Teva USA, at 1090 Horsham Road, North Wales, Pennsylvania 19454.

9. Actavis UT, Teva USA, and Teva Israel work in active concert with respect to the development, regulatory approval, importing, marketing, sale, and distribution of pharmaceutical products, including the product described in Abbreviated New Drug Application No. 210019 (the "ANDA").

JURISDICTION AND VENUE

10. 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 and 1400(b).

11. This Court has personal jurisdiction over Actavis UT, Teva USA, and Teva Israel because these entities file 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.

12. Actavis UT, Teva USA, and Teva Israel operate as an integrated business, as evidenced by Teva Israel's 2017 Form 20-F, which indicates that Teva Israel files a single annual report to the U.S. Securities and Exchange Commission for itself and its subsidiaries, including Teva USA and Actavis UT.

13. Actavis UT, formerly known as Watson Laboratories, Inc., was a party to previous litigation in this district involving the filing of an ANDA to market a generic version of Epiduo® Gel (adapalene and benzoyl peroxide gel, 0.1% / 2.5%) in the United States. *See Galderma Labs., L.P. v. Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc.*, 3:12-cv-02563-K (N.D. Tex.). Moreover, Actavis UT's affiliate, Actavis Mid Atlantic LLC, has also previously been involved in litigation in this district involving the filing of an ANDA to market a generic version of Epiduo® Gel in the United States. *See Galderma Labs., L.P. v. Actavis Mid Atlantic LLC*, 3:12-cv-2038-K (N.D. Tex.). Actavis UT, Teva USA, and Teva Israel are currently involved in litigation in this district involving the filing of an ANDA to market a generic version of Epiduo® Forte Gel (adapalene and benzoyl peroxide gel, 0.3% / 2.5%) in the United States. *See Galderma Labs., L.P. v. Actavis Labs UT, Inc. et al.*, 3:17-cv-903-K (N.D. Tex.).

14. Teva also 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. Teva intends to sell the infringing product in or for distribution in this district upon approval by the FDA. Teva

has thus purposefully targeted its conduct to cause harm in the State of Texas, and particularly in this district.

15. Venue is proper in this district because the claims asserted herein arise out of an act of patent infringement—Teva'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 '069 Patent

16. On January 29, 2013, the USPTO issued the '069 Patent, entitled "Compositions Comprising At Least One Aqueous Phase and At Least One Fatty Phase Which Comprises Avermectin Compounds," to GSA.

17. The '069 Patent is valid, enforceable, and has not expired.

B. The '816 Patent

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

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

C. The '587 Patent

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

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

D. The ˈ117 Patent

22. On January 12, 2016, the USPTO issued the ˈ117 Patent, entitled "Treatment of Inflammatory Lesions of Rosacea With Ivermectin," to GSA.

23. The ˈ117 Patent is valid, enforceable, and has not expired.

E. The ˈ118 Patent

24. On January 12, 2016, the USPTO issued the ˈ118 Patent, entitled "Treatment of Papulopustular Rosacea With Ivermectin," to GSA.

25. The ˈ118 Patent is valid, enforceable, and has not expired.

F. Soolantra® (Ivermectin) Cream, 1%

26. 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 ˈ816 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%.

G. Tevaˈs Infringement

27. Teva is in the business of developing, manufacturing, and marketing generic pharmaceutical products.

28. On December 30, 2016, Teva filed an application seeking FDA approval to sell a generic version of Soolantra® (ivermectin) Cream, 1%.

29. During the process of preparing such application, Teva 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%.

30. Teva submitted ANDA No. 210019 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.

31. 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.

32. On or about March 10, 2017, Teva sent the Paragraph IV Certification to GLP in Fort Worth, Texas and to GSA. Through the Paragraph IV Certification, Teva first notified Plaintiffs that Teva 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 Teva's opinion, the claims of the '816 Patent, '587 Patent, '117 Patent, and '118 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.

33. Teva was aware of at least the '816 Patent, '587 Patent, '117 Patent, and '118 Patent when it filed the ANDA and/or sent the Paragraph IV Certification.

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

35. Teva 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. 8,362,069

36. Plaintiffs incorporate paragraphs 1 through 35 above by reference as if fully set forth herein.

37. The ˈ069 Patent is valid, enforceable, and has not expired.

38. The Accused Product and/or its use as directed infringes one or more of the claims of the ˈ069 Patent, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Teva infringed the ˈ069 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the ˈ069 Patent.

39. Teva will induce infringement of one or more claims of the ˈ069 Patent—in violation of Plaintiffsˈ 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 ˈ069 Patent by users of the Accused Product.

40. Teva seeks approval of at least one indication for the Accused Product that is claimed in the ˈ069 Patent.

41. Teva intends that physicians will prescribe, and patients will use, the Accused Product in accordance with the indication(s) sought by Teva and will therefore infringe one or more claims of the ˈ069 Patent under 35 U.S.C. § 271(b).

42. In addition, pursuant to the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355 *et seq.*, Tevaˈs 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)].

43. As such, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed the ʹ069 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the ʹ069 Patent.

44. As a result of Teva's infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the ʹ069 Patent if made, used as directed, sold, offered for sale, or imported during the term of the ʹ069 Patent.

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

46. As a result of Teva's infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Teva and all those in privity or acting in concert with Teva from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the ʹ069 Patent, or from otherwise infringing or inducing the infringement of the ʹ069 Patent.

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

47. Plaintiffs incorporate paragraphs 1 through 46 above by reference as if fully set forth herein.

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

49. The Accused Product and/or its use as directed infringes one or more of the claims of the ʹ816 Patent, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Teva 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.

50. Teva will induce infringement of one or more claims of the ʹ816 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 of the ʹ816 Patent by users of the Accused Product.

51. Teva seeks approval of at least one indication for the Accused Product that is claimed in the ʹ816 Patent.

52. Teva intends that physicians will prescribe, and patients will use, the Accused Product in accordance with the indication(s) sought by Teva and will therefore infringe one or more claims of the ʹ816 Patent under 35 U.S.C. § 271(b).

53. In addition, pursuant to the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355 *et seq.*, Tevaʹs 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)].

54. As such, under 35 U.S.C. § 271(e)(2)(A), Teva has 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.

55. As a result of Teva'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.

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

57. As a result of Teva's infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Teva and all those in privity or acting in concert with Teva from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the '816 Patent, or from otherwise infringing or inducing the infringement of the '816 Patent.

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

58. Plaintiffs incorporate paragraphs 1 through 57 above by reference as if fully set forth herein.

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

60. The Accused Product and/or its use as directed infringes one or more of the claims of the '587 Patent, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Teva infringed the '587 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '587 Patent.

61. Teva will induce infringement of one or more claims of the '587 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 '587 Patent by users of the Accused Product.

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

63. Teva intends that physicians will prescribe, and patients will use, the Accused Product in accordance with the indication(s) sought by Teva and will therefore infringe one or more claims of the ʹ587 Patent under 35 U.S.C. § 271(b).

64. In addition, pursuant to the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355 *et seq.*, Teva'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)].

65. As such, under 35 U.S.C. § 271(e)(2)(A), Teva 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.

66. As a result of Teva's 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.

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

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

manufacturing, selling, offering to sell, or importing the Accused Product during the term of the '587 Patent, or from otherwise infringing or inducing the infringement of the '587 Patent.

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

69. Plaintiffs incorporate paragraphs 1 through 68 above by reference as if fully set forth herein.

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

71. The Accused Product and/or its use as directed infringes one or more of the claims of the '117 Patent, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Teva 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.

72. Teva 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 of the '117 Patent by users of the Accused Product.

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

74. Teva intends that physicians will prescribe, and patients will use, the Accused Product in accordance with the indication(s) sought by Teva and will therefore infringe one or more claims of the '117 Patent under 35 U.S.C. § 271(b).

75. In addition, pursuant to the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355 *et seq.*, Teva'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)].

76. As such, under 35 U.S.C. § 271(e)(2)(A), Teva 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.

77. As a result of Teva's 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.

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

79. As a result of Teva's infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Teva and all those in privity or acting in concert with Teva 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 V:
INFRINGEMENT OF U.S. PATENT NO. 9,233,118

80. Plaintiffs incorporate paragraphs 1 through 79 above by reference as if fully set forth herein.

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

82. The Accused Product and/or its use as directed infringes one or more of the claims of the ʹ118 Patent, either literally or under the doctrine of equivalents. As such, under 35

U.S.C. § 271(e)(2)(A), Teva 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.

83. Teva will induce infringement of one or more claims of the ʹ118 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 of the ʹ118 Patent by users of the Accused Product.

84. Teva seeks approval of at least one indication for the Accused Product that is claimed in the ʹ118 Patent.

85. Teva intends that physicians will prescribe, and patients will use, the Accused Product in accordance with the indication(s) sought by Teva and will therefore infringe one or more claims of the ʹ118 Patent under 35 U.S.C. § 271(b).

86. In addition, pursuant to the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355 *et seq.*, Tevaʹs 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)].

87. As such, under 35 U.S.C. § 271(e)(2)(A), Teva has 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.

88. As a result of Teva'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.

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

90. As a result of Teva's infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Teva and all those in privity or acting in concert with Teva 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 Teva 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 Teva'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 Teva 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 Teva 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 Teva'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: April 21, 2017

Respectfully submitted,

/s/ Jamil N. Alibhai

Jamil N. Alibhai
State Bar No. 00793248
jalibhai@munckwilson.com
Michael C. Wilson
State Bar No. 21704590
mwilson@munckwilson.com
Daniel E. Venglarik
State Bar No. 00791851
dvenglarik@munckwilson.com
Kelly P. Chen
Texas State Bar No. 24062664
kchen@munckwilson.com
Jordan C. Strauss
Texas State Bar No. 24088480
jstrauss@munckwilson.com
MUNCK WILSON MANDALA, LLP
12770 Coit Road
Dallas, Texas 75251
Telephone: 972-628-3600
Facsimile: 972-628-3616

ATTORNEYS FOR PLAINTIFFS GALDERMA LABORATORIES, L.P., GALDERMA S.A., AND NESTLÉ SKIN HEALTH S.A.

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