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. 3:12-cv-2038**
v.	§	
ACTAVIS MID ATLANTIC LLC,	§	
Defendant.	§	

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 Defendant ACTAVIS MID ATLANTIC LLC 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% (hereafter "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 ointment 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 Louisiana 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"), and U.S. Patent No. 8,129,362 (the "'362 Patent"). 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."

4. Actavis Mid Atlantic LLC ("Actavis") is a Delaware limited liability company with its principal place of business at 60 Columbia Road, Building B, Morristown, New Jersey 07960. Actavis may be served with process by and through its registered agent for service of process United Corporation Services, Inc., 874 Walker Road, Suite C, Dover, Delaware 19904.

JURISDICTION AND VENUE

5. 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).

6. This Court has personal jurisdiction over Actavis because Actavis sells products for distribution throughout the United States and, on information and belief, regularly conducts business in the State of Texas. Actavis 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 Galderma L.P. would be injured by such actions in this district, and delivered its Paragraph IV Certification to Galderma L.P. in this district. Moreover, on information and belief, Actavis intends to sell the infringing product in or for distribution in this district upon approval by the FDA. Actavis has thus purposefully targeted its conduct to cause harm in the State of Texas and this district.

7. Venue is proper in this district because the claims asserted herein arise out of an act of patent infringement (*i.e.*, Actavis's 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 Actavis could file suit seeking a declaration of non-infringement in connection with the ANDA.

BACKGROUND FACTS

A. The '186 Patent

8. 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.

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

B. The '202 Patent

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

11. The ʹ202 Patent is valid, enforceable, and has not expired.

C. The ʹ644 Patent

12. On December 6, 2011, the USPTO issued the ʹ644 Patent, entitled "Combinations of Adapalene and Benzoyl Peroxide for Treating Acne Lesions," to Galderma R&D.

13. The ʹ644 Patent is valid, enforceable, and has not expired.

D. The ʹ537 Patent

14. On December 26, 2011, the USPTO issued the ʹ537 Patent, entitled "Combinations of Adapalene and Benzoyl Peroxide for Treating Acne Lesions," to Galderma R&D.

15. The ʹ537 Patent is valid, enforceable, and has not expired.

E. The ʹ618 Patent

16. On January 31, 2012, the USPTO issued the ʹ618 Patent, entitled "Dermatological/Cosmetic Gels Comprising At Least One Retinoid and/or Retinoid Salt and Benzoyl Peroxide," to Galderma R&D.

17. The ʹ618 Patent is valid, enforceable, and has not expired.

F. The ʹ362 Patent

18. On March 6, 2012, the USPTO issued the ʹ362 Patent, entitled "Combination/ Association of Adapalene and Benzoyl Peroxide for Treating Acne Lesions," to Galderma R&D.

19. The ʹ362 Patent is valid, enforceable, and has not expired.

G. Epiduo® Gel

20. 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 ʹ186 Patent, ʹ202 Patent, ʹ644 Patent, ʹ537 Patent, ʹ618 Patent, and ʹ362 Patent 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%.

21. Galderma S.A. and Galderma R&D have granted Galderma L.P. the exclusive right to distribute Epiduo® Gel in the United States.

H. Actavis's Infringement

22. Actavis is in the business of developing, manufacturing, and marketing generic pharmaceutical products.

23. On information and belief, Actavis reviewed the '186 Patent, '202 Patent, '644 Patent, '537 Patent, '618 Patent, and '362 Patent and certain commercial and economic information relating to Epiduo® Gel, including estimates of the revenues generated by the sale of Epiduo® Gel.

24. On or about December 30, 2011, Actavis submitted Abbreviated New Drug Application No. 203790 (the "ANDA") seeking approval to engage in the commercial manufacture, use, and sale of generic Adapalene and Benzoyl Peroxide Gel, 0.1% / 2.5% ("the Accused Product") prior to the expiration of the '186 Patent, '202 Patent, '644 Patent, '537 Patent, '618 Patent, and '362 Patent.

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

26. On or about May 14, 2012, Actavis sent a letter (the "Certification Letter") to Galderma L.P. in Fort Worth, Texas, and to Galderma R&D in France. Through the Certification Letter, Actavis first notified Plaintiffs that Actavis 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 Actavis's opinion, the claims of the '186 Patent, '202 Patent, '644 Patent, '537 Patent, '618 Patent, and '362 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. Actavis was aware of the '186 Patent, '202 Patent, '644 Patent, '537 Patent, '618 Patent, and '362 Patent when it filed the ANDA and/or sent the Certification Letter.

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

29. On information and belief, Actavis 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, including this District), in the event that FDA approves the ANDA.

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

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

31. The '186 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 '186 Patent, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Actavis infringed the '186 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '186 Patent.

33. As a result of Actavis'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.

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

35. Plaintiffs incorporate paragraphs 1 through 34 above by reference as if fully set forth herein.

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

37. 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), Actavis infringed the '202 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '202 Patent.

38. Upon information and belief, Actavis 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.

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

40. On information and belief, Actavis knows that physicians will prescribe, and patients will use, the Accused Product in accordance with the indication(s) sought by Actavis and will therefore infringe one or more claims of the ʹ202 Patent under 35 U.S.C. § 271(b).

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

42. As a result of Actavisʹs infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the ʹ202 Patent if made, used as directed, sold, offered for sale, or imported during the term of the ʹ202 Patent.

43. As a result of Actavisʹs infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Actavis and all those in privity with or acting in concert with Actavis from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the ʹ202 Patent, or from otherwise infringing or inducing the infringement of the ʹ202 Patent.

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

44. Plaintiffs incorporate paragraphs 1 through 43 above by reference as if fully set forth herein.

45. The ʹ644 Patent is valid, enforceable, and has not expired.

46. The Accused Product and/or its use as directed infringes one or more of the claims of the ʹ644 Patent, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Actavis infringed the ʹ644 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the ʹ644 Patent.

47. Upon information and belief, Actavis will induce infringement of one or more claims of the ʹ644 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 ʹ644 Patent by users of the Accused Product.

48. On information and belief, Actavis seeks approval of at least one indication for the Accused Product that is claimed in the ʹ644 Patent.

49. On information and belief, Actavis knows that physicians will prescribe, and patients will use, the Accused Product in accordance with the indication(s) sought by Actavis and will therefore infringe one or more claims of the ʹ644 Patent under 35 U.S.C. § 271(b).

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

51. As a result of Actavisʹs infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the ʹ644 Patent if made, used as directed, sold, offered for sale, or imported during the term of the ʹ644 Patent.

52. As a result of Actavisʹs infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Actavis and all those in privity with or acting in concert with Actavis from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the ʹ644 Patent, or from otherwise infringing or inducing the infringement of the ʹ644 Patent.

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

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

54. The ʹ537 Patent is valid, enforceable, and has not expired.

55. The Accused Product and/or its use as directed infringes one or more of the claims of the ʹ537 Patent, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Actavis infringed the ʹ537 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the ʹ537 Patent.

56. Upon information and belief, Actavis will induce infringement of one or more claims of the ʹ537 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 ʹ537 Patent by users of the Accused Product.

57. On information and belief, Actavis seeks approval of at least one indication for the Accused Product that is claimed in the ʹ537 Patent.

58. On information and belief, Actavis knows that physicians will prescribe, and patients will use, the Accused Product in accordance with the indication(s) sought by Actavis and will therefore infringe one or more claims of the ʹ537 Patent under 35 U.S.C. § 271(b).

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

60. As a result of Actavisʹs infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the ʹ537 Patent if made, used as directed, sold, offered for sale, or imported during the term of the ʹ537 Patent.

61. As a result of Actavisʹs infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Actavis and all those in privity with or acting in

concert with Actavis from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the ʹ537 Patent, or from otherwise infringing or inducing the infringement of the ʹ537 Patent.

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

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

63. The ʹ618 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 ʹ618 Patent, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Actavis infringed the ʹ618 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the ʹ618 Patent.

65. Upon information and belief, Actavis will induce infringement of one or more claims of the ʹ618 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 ʹ618 Patent by users of the Accused Product.

66. On information and belief, Actavis seeks approval of at least one indication for the Accused Product that is claimed in the ʹ618 Patent.

67. On information and belief, Actavis knows that physicians will prescribe, and patients will use, the Accused Product in accordance with the indication(s) sought by Actavis and will therefore infringe one or more claims of the ʹ618 Patent under 35 U.S.C. § 271(b).

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

69. As a result of Actavis'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.

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

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

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

73. 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), Actavis infringed the '362 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '362 Patent.

74. Upon information and belief, Actavis 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 ˈ362 Patent by users of the Accused Product.

75. On information and belief, Actavis seeks approval of at least one indication for the Accused Product that is claimed in the ˈ362 Patent.

76. On information and belief, Actavis knows that physicians will prescribe, and patients will use, the Accused Product in accordance with the indication(s) sought by Actavis and will therefore infringe one or more claims of the ˈ362 Patent under 35 U.S.C. § 271(b).

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

78. As a result of Actavisˈs infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the ˈ362 Patent if made, used as directed, sold, offered for sale, or imported during the term of the ˈ362 Patent.

79. As a result of Actavisˈs infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Actavis and all those in privity with or acting in concert with Actavis from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the ˈ362 Patent, or from otherwise infringing or inducing the infringement of the ˈ362 Patent.

DEMAND FOR JURY TRIAL

In the event Actavis 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 Actavis'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 Patent, '202 Patent, '644 Patent, '537 Patent, '618 Patent, and '362 Patent, 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 Actavis has infringed the '186 Patent, '202 Patent, '644 Patent, '537 Patent, '618 Patent, and '362 Patent 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 Patent, '202 Patent, '644 Patent, '537 Patent, '618 Patent, and '362 Patent, 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 Actavis 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 Patent, '202 Patent, '644 Patent, '537 Patent, '618 Patent, and '362

Patent, 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 Actavis'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 Patent, '202 Patent, '644 Patent, '537 Patent, '618 Patent, and '362 Patent, 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/ Michael C. Wilson

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