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. 3:15-CV-1416-B**
v.	§	
GLENMARK GENERICS INC., USA and GLENMARK GENERICS LTD.	§	
Defendant.	§	

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, GALDERMA LABORATORIES, L.P., GALDERMA S.A., and GALDERMA RESEARCH & DEVELOPMENT, S.N.C., file this First Amended Complaint for Patent Infringement against Defendants GLENMARK GENERICS INC., USA and GLENMARK GENERICS LTD. (collectively "Glenmark") 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 9 years old.

2. Galderma S.A. is a Swiss company with its principal place of business at World Trade Center, Avenue de Gratta-Paille 2, 1018 Lausanne, Switzerland. Galderma S.A. and/or its affiliates are 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. 8,071,644 (the "'644 Patent"), U.S. Patent No. 8,080,537 (the "'537 Patent"), U.S. Patent No. 8,129,362 (the "'362 Patent"), U.S. Patent No. 8,445,543 (the "'543 Patent"), and U.S. Patent No. 8,809,305 (the "'305 Patent"). A copy of the '644 Patent is attached as Exhibit "A." A copy of the '537 Patent is attached as Exhibit "B." A copy of the '362 Patent is attached as Exhibit "C." A copy of the '543 Patent is attached as Exhibit "D." A copy of the '305 Patent is attached as Exhibit "E."

4. Glenmark Generics Inc., USA ("Glenmark USA") is a Delaware corporation with its principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430. Glenmark may be served with process at its principal place of business.

5. Glenmark Generics Ltd. ("Glenmark Ltd.") is a corporation organized and existing under the laws of India, having a principal place of business at Wing A, Glenmark House, HDO-Corporate Building, Bd Sawant Marg Chakala Off Western Express Highway, Mumbai, 400099, Maharashtra, India. Upon information and belief, Glenmark Ltd. may be served with process through its agent, Glenmark USA.

6. On information and belief, Defendant Glenmark USA, on behalf of Glenmark Ltd., assembled and caused to be filed with the United States Food and Drug Administration ("FDA"), pursuant to 21 U.S.C. § 355(j) (Section 505(j) of the Federal Food, Drug and Cosmetic

Act), Abbreviated New Drug Application ("ANDA") No. 208108 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"). Glenmark USA acted in concert with Glenmark Ltd. to develop and seek approval from the FDA to sell the Accused Product throughout the United States, Texas, and this judicial district. Glenmark USA is listed as Glenmark Ltd.'s authorized U.S. agent and submitted the ANDA on behalf of Glenmark Ltd. On information and belief, Glenmark USA participated in the preparation and submission of the ANDA and will benefit directly and indirectly upon the approval of the ANDA.

JURISDICTION AND VENUE

7. 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).

8. This Court has personal jurisdiction over Glenmark because Glenmark sells products for distribution throughout the United States and, on information and belief, regularly conducts business in the State of Texas. Glenmark 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, Glenmark intends to sell the infringing product in or for distribution in this district upon approval by the FDA. Glenmark has thus purposefully targeted its conduct to cause harm in the State of Texas and this district.

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

BACKGROUND FACTS

A. The '644 Patent

10. 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.

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

B. The '537 Patent

12. 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.

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

C. The '362 Patent

14. 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.

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

D. The '543 Patent

16. 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.

17. The ʹ543 Patent is valid, enforceable, and has not expired.

E. The ʹ305 Patent

18. On August 19, 2014, the USPTO issued the ʹ305 Patent, entitled "Administration of Adapalene and Benzoyl Peroxide for the Long-Term Treatment of Acne Vulgaris," to Galderma R&D.

19. The ʹ305 Patent is valid, enforceable, and has not expired.

F. 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 ʹ644 Patent, ʹ537 Patent, ʹ362 Patent, ʹ543 Patent, and ʹ305 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.

G. Glenmarkʹs Infringement

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

23. On information and belief, Glenmark reviewed the ʹ644 Patent, ʹ537 Patent, ʹ362 Patent, ʹ543 Patent, and ʹ305 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 November 26, 2014, Glenmark submitted ANDA No. 208108 seeking approval to engage in the commercial manufacture, use, and sale of generic Adapalene

and Benzoyl Peroxide Gel, 0.1% / 2.5% prior to the expiration of the ʹ644 Patent, ʹ537 Patent, ʹ362 Patent, ʹ543 Patent, and ʹ305 Patent.

25. The Accused Product that is the subject of the ANDA directly and indirectly infringes one or more claims of the ʹ644 Patent, ʹ537 Patent, ʹ362 Patent, ʹ543 Patent, and ʹ305 Patent.

26. On or about March 23, 2015, Glenmark 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, Glenmark first notified Plaintiffs that Glenmark 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 Glenmarkʹs opinion, the claims of the ʹ644 Patent, ʹ537 Patent, ʹ362 Patent, ʹ543 Patent, and ʹ305 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. Glenmark was aware of the ʹ644 Patent, ʹ537 Patent, ʹ362 Patent, ʹ543 Patent, and ʹ305 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 Glenmarkʹs notice of the ANDA containing the Paragraph IV certification.

29. On information and belief, Glenmark 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. 8,071,644

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

31. The ʹ644 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 ʹ644 Patent. As such, under 35 U.S.C. § 271(e)(2)(A), Glenmark 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.

33. Upon information and belief, Glenmark 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.

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

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

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

37. As a result of Glenmarkʹs 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.

38. As a result of Glenmark's infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Glenmark and all those in privity with or acting in concert with Glenmark 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 II:
INFRINGEMENT OF U.S. PATENT NO. 8,080,537

39. Plaintiffs incorporate paragraphs 1 through 38 above by reference as if fully set forth herein.

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

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

42. Upon information and belief, Glenmark 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.

43. On information and belief, Glenmark seeks approval of at least one indication for the Accused Product that is claimed in the '537 Patent.

44. On information and belief, Glenmark knows that physicians will prescribe, and patients will use, the Accused Product in accordance with the indication(s) sought by Glenmark and will therefore infringe one or more claims of the '537 Patent under 35 U.S.C. § 271(b).

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

46. As a result of Glenmark'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.

47. As a result of Glenmark's infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Glenmark and all those in privity with or acting in concert with Glenmark 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 III:
INFRINGEMENT OF U.S. PATENT NO. 8,129,362

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

49. The '362 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 '362 Patent. As such, under 35 U.S.C. § 271(e)(2)(A), Glenmark 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.

51. Upon information and belief, Glenmark 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.

52. On information and belief, Glenmark seeks approval of at least one indication for the Accused Product that is claimed in the ʹ362 Patent.

53. On information and belief, Glenmark knows that physicians will prescribe, and patients will use, the Accused Product in accordance with the indication(s) sought by Glenmark and will therefore infringe one or more claims of the ʹ362 Patent under 35 U.S.C. § 271(b).

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

55. As a result of Glenmarkʹs infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the ʹ362 Patent if made, used as directed, sold, offered for sale, or imported during the term of the ʹ362 Patent.

56. As a result of Glenmark's infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Glenmark and all those in privity with or acting in concert with Glenmark from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the ʹ362 Patent, or from otherwise infringing or inducing the infringement of the ʹ362 Patent.

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

57. Plaintiffs incorporate paragraphs 1 through 56 above by reference as if fully set forth herein.

58. The ʹ543 Patent is valid, enforceable, and has not expired.

59. The Accused Product and/or its use as directed infringes one or more of the claims of the ʹ543 Patent. As such, under 35 U.S.C. § 271(e)(2)(A), Glenmark infringed the

'543 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '543 Patent.

60. Upon information and belief, Glenmark 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.

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

62. On information and belief, Glenmark knows that physicians will prescribe, and patients will use, the Accused Product in accordance with the indication(s) sought by Glenmark and will therefore infringe one or more claims of the '543 Patent under 35 U.S.C. § 271(b).

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

64. As a result of Glenmark'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.

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

COUNT V:
INFRINGEMENT OF U.S. PATENT NO. 8,809,305

66. Plaintiffs incorporate paragraphs 1 through 65 above by reference as if fully set forth herein.

67. The '305 Patent is valid, enforceable, and has not expired.

68. In at least some circumstances, use of the Accused Product and/or its use as directed infringes one or more of the claims of the '305 Patent. As such, under 35 U.S.C. § 271(e)(2)(A), Glenmark infringed the '305 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '305 Patent.

69. Upon information and belief, Glenmark will induce infringement of one or more claims of the '305 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 '305 Patent by users of the Accused Product.

70. On information and belief, Glenmark seeks approval of the Accused Product that will result in infringement of methods claimed in the '305 Patent.

71. On information and belief, Glenmark knows that physicians will prescribe, and patients will use, the Accused Product in accordance with the methods claimed in the '305 Patent under 35 U.S.C. § 271(b).

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

73. As a result of Glenmark's infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the '305 Patent if made, used as directed, sold, offered for sale, or imported during the term of the '305 Patent.

74. As a result of Glenmark's infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Glenmark and all those in privity with or acting in concert with Glenmark from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the '305 Patent, or from otherwise infringing or inducing the infringement of the '305 Patent.

DEMAND FOR JURY TRIAL

In the event Glenmark 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 Glenmark'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 '644 Patent, '537 Patent, '362 Patent, '543 Patent, and '305 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 Glenmark has infringed the '644 Patent, '537 Patent, '362 Patent, '543 Patent, and '305 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 '644 Patent, '537 Patent, '362 Patent, '543 Patent, and '305 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 Glenmark 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 '644 Patent, '537 Patent, '362 Patent, '543 Patent, and '305 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 Glenmark'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 '644 Patent, '537 Patent, '362 Patent, '543 Patent, and '305 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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