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,	§	
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 GALDERMA RESEARCH & DEVELOPMENT, S.N.C. (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, "Actavis" 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. As Galderma S.A.'s ("GSA") exclusive sub-licensee, GLP holds the exclusive right to use, manufacture, and sell Galderma's patented products in the United States, including Epiduo® Forte Gel, under FDA approval of New Drug Application ("NDA") No. 207917, approved July 15, 2015. Moreover,

GLP is responsible for seeking regulatory approvals of Galderma's products in the United States, and is the sole owner of NDA No. 207917.

2. GSA is a Swiss company with its principal place of business at World Trade Center, Avenue de Gratta-Paille 2, 1018 Lausanne, Switzerland. As Galderma Research & Development, S.N.C.'s ("GR&D") exclusive licensee, GSA holds exclusive rights to use, manufacture, and sell Galderma's patented products outside of France, including Epiduo® Forte (adapalene and benzoyl peroxide) Gel, 0.3% / 2.5% ("Epiduo® Forte Gel"). GSA's exclusive license also includes the right and authority to grant an exclusive sub-license, which GSA has granted to GLP as described above.

3. GR&D is a French corporation with its principal place of business at 2400 Route Des Colles, Les Templiers, Biot, France 06410. GR&D is the current owner of U.S. Patent No. 8,445,543 (the "'543 Patent"), U.S. Patent No. 8,785,420 (the "'420 Patent"), and U.S. Patent No. 8,809,305 (the "'305 Patent"). A copy of the '543 Patent is attached as Exhibit "A." A copy of the '420 Patent is attached as Exhibit "B." A copy of the '305 Patent is attached as Exhibit "C."

4. Epiduo® Forte Gel is a topical ointment prescription drug that combines a retinoid (adapalene) and an antimicrobial (benzoyl peroxide) for the treatment of acne vulgaris (including severe acne) in people who are at least 12 years old.

5. 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 Rodney 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.

6. 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 Rodney 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.

7. 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.

8. 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. 209641 (the "ANDA").

JURISDICTION AND VENUE

9. 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).

10. 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.

11. 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.

12. 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.). In that matter, this Court also evaluated Galderma's patents covering Epiduo® Gel, including the '543 Patent, asserted in this suit.

13. 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 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. 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 particularly in this district.

14. Venue is proper in this district because the claims asserted herein arise out of an act of patent infringement—Actavis'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 '543 Patent

15. On May 21, 2013, the USPTO issued the '543 Patent, entitled "Combinations of Adapalene and Benzoyl Peroxide for Treating Acne Lesions," to GR&D. GR&D exclusively licensed the '543 Patent to GSA. GSA exclusively sublicensed its rights under the '543 Patent in the United States to GLP.

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

B. The '420 Patent

17. On July 22, 2014, the USPTO issued the '420 Patent, entitled "Combination/Association of Adapalene and Benzoyl Peroxide for Treating Acne Lesions," to GR&D. GR&D exclusively licensed the '420 Patent to GSA. GSA exclusively sublicensed its rights under the '420 Patent in the United States to GLP.

18. The '420 Patent is valid, enforceable, and has not expired.

C. The ˈ305 Patent

19. On August 19, 2014, the USPTO issued the ˈ305 Patent, entitled "Administration of Adapalene and Benzoyl Peroxide for the Long-Term Treatment of Acne Vulgaris," to GR&D. GR&D exclusively licensed the ˈ305 Patent to GSA. GSA exclusively sublicensed its rights under the ˈ305 patent in the United States to GLP.

20. The ˈ305 Patent is valid, enforceable, and has not expired.

D. Epiduo® Forte Gel

21. GLP is the exclusive owner of NDA No. 207917 giving it sole permission to market and sell Epiduo® Forte Gel in the United States. On July 15, 2015, GLP obtained FDA approval to market Epiduo® Forte Gel. The ˈ543 Patent, ˈ420 Patent, and ˈ305 Patent are listed in the FDA publication entitled, "Approved Drug Products With Therapeutic Equivalence Evaluations" (known as the "Orange Book") as covering Epiduo® Forte (adapalene and benzoyl peroxide) Gel, 0.3% / 2.5%.

22. GR&D has granted GSA, as exclusive licensee, the exclusive right to use, manufacture, and sell Epiduo® Forte Gel outside of France, including the right to sub-license to GLP.

23. GR&D and GSA have granted GLP, as exclusive sub-licensee, the exclusive right to use, manufacture, and sell Epiduo® Forte Gel in the United States.

E. Actavisˈs Infringement

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

25. Prior to February 15, 2017, Actavis decided to file an application seeking FDA approval to sell a generic version of Epiduo® Forte Gel.

26. During the process of preparing such application, Actavis reviewed the ʹ543 Patent, ʹ420 Patent, ʹ305 Patent, and certain commercial and economic information relating to Epiduo® Forte Gel.

27. Actavis submitted ANDA No. 209641 seeking approval to engage in the commercial manufacture, use, and sale of generic adapalene and benzoyl peroxide gel, 0.3% / 2.5% (the "Accused Product" or "Infringing Product") prior to the expiration of the ʹ543 Patent, ʹ420 Patent, and ʹ305 Patent.

28. The Accused Product that is the subject of the ANDA will directly and indirectly infringe one or more claims of the ʹ543 Patent, ʹ420 Patent, and ʹ305 Patent.

29. On or about February 15, 2017, Actavis sent the Paragraph IV Certification to GLP in Fort Worth, Texas and to GR&D. Through the Paragraph IV Certification, 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) that, in Actavisʹs opinion, the claims of the ʹ543 Patent, ʹ420 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.

30. Actavis was aware of the ʹ543 Patent, ʹ420 Patent, and ʹ305 Patent when it filed the ANDA and/or sent the Paragraph IV Certification.

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

32. 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 and this District), in the event that the FDA approves the ANDA.

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

33. Plaintiffs incorporate paragraphs 1 through 32 above by reference as if fully set forth herein.

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

35. The Accused Product and/or its use as directed infringes at least claim 1 of the ʹ543 Patent. As such, under 35 U.S.C. § 271(e)(2)(A), Actavis infringed the ʹ543 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the ʹ543 Patent.

36. Actavis will induce infringement of one or more claims of the ʹ543 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 ʹ543 Patent by users of the Accused Product.

37. Actavis seeks approval of at least one indication for the Accused Product that is claimed in the ʹ543 Patent.

38. Actavis intends 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 ʹ543 Patent under 35 U.S.C. § 271(b).

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

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

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

41. As a result of Actavis'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.

42. 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.

43. As a result of Actavis's infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Actavis and all those in privity or acting in concert with Actavis 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 II:
INFRINGEMENT OF U.S. PATENT NO. 8,785,420

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

45. The '420 Patent is valid, enforceable, and has not expired.

46. The Accused Product and/or its use as directed infringes at least claim 1 of the ˈ420 Patent. As such, under 35 U.S.C. § 271(e)(2)(A), Actavis infringed the ˈ420 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the ˈ420 Patent,

47. Actavis will induce infringement of one or more claims of the ˈ420 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 ˈ420 Patent by users of the Accused Product.

48. Actavis seeks approval of at least one indication for the Accused Product that is claimed in the ˈ420 Patent.

49. Actavis intends 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 ˈ420 Patent under 35 U.S.C. § 271(b).

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

51. As such, under 35 U.S.C. § 271(e)(2)(A), Actavis has infringed the ˈ420 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the ˈ420 Patent.

52. As a result of Actavis's infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the '420 Patent if made, used as directed, sold, offered for sale, or imported during the term of the '420 Patent.

53. 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.

54. As a result of Actavis's infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Actavis and all those in privity or acting in concert with Actavis from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the '420 Patent, or from otherwise infringing or inducing the infringement of the '420 Patent.

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

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

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

57. Use of the Accused Product will infringe at least claim 1 of the '305 Patent. Under 35 U.S.C. § 271(e)(2)(A), Actavis 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.

58. Actavis intends that physicians will prescribe, and that patients will use, the Accused Product in accordance with the methods claimed in the '305 Patent under 35 U.S.C. § 271(b).

59. Actavis will induce infringement of one or more claims of the ˈ305 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 ˈ305 Patent by users of the Accused Product.

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

61. As such, under 35 U.S.C. § 271(e)(2)(A), Actavis has infringed the ˈ305 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the ˈ305 Patent.

62. As a result of Actavisˈs infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the ˈ305 Patent if made, used as directed, sold, offered for sale, or imported during the term of the ˈ305 Patent.

63. 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.

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

during the term of the ˈ305 Patent, or from otherwise infringing or inducing the infringement of the ˈ305 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 Actavisˈs 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 ˈ543 Patent, ˈ420 Patent, and ˈ305 Patent, including any patent extensions and any additional periods of exclusivity, would constitute infringement of such patents in violation of Plaintiffsˈ patent rights;

(B) A declaration, pursuant to 35 U.S.C. § 271(e)(2)(A), that Actavis has infringed the ˈ543 Patent, ˈ420 Patent, and ˈ305 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 ˈ543 Patent, ˈ420 Patent, and ˈ305 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 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 ʹ543 Patent, ʹ420 Patent, and ʹ305 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 Actavisʹs 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 ʹ543 Patent, ʹ420 Patent, and ʹ305 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.

Dated: March 30, 2017

Respectfully submitted,

/s/ Jamil N. Alibhai

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