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. _____**
TARO PHARMACEUTICALS U.S.A., INC., TARO PHARMACEUTICAL INDUSTRIES LTD., and TARO PHARMACEUTICALS INC.,	§	
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 TARO PHARMACEUTICALS U.S.A., INC. ("Taro USA"), TARO PHARMACEUTICAL INDUSTRIES LTD. ("Taro Israel"), and TARO PHARMACEUTICALS INC. ("Taro Canada") (collectively, "Taro" or "Defendants") as follows:

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 exclusive beneficial holder of rights to market Epiduo® Forte (adapalene and benzoyl peroxide) Gel, 0.3% / 2.5% ("Epiduo® Forte Gel") under FDA approval of New Drug Application ("NDA") No. 207917, approved July 15, 2015, and is owner of this NDA.

Galderma L.P. has the exclusive right from Galderma Research & Development, S.N.C. ("Galderma R&D") to sell and offer to sell Epiduo® Forte Gel in the United States. 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.

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 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. 8,445,543 (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. Taro Pharmaceuticals U.S.A., Inc. ("Taro USA") is a corporation organized and existing under the laws of the State of New York with its principal place of business at 3 Skyline Drive, Hawthorne, New York, 10532. Taro USA may be served with process by and through its registered agent for service of process, C T Corporation System, 111 Eighth Avenue, New York, New York, 10011. Taro USA is a wholly-owned subsidiary of Taro Israel and acts at the direction of, under the control of, and for the benefit of Taro Israel.

5. Taro Pharmaceuticals Inc. ("Taro Canada") is a Canadian corporation with its principal place of business at 130 East Drive, Brampton, Ontario, L6T 1C1, Canada. Taro

Canada may be served with process by and through Taro USA, at 3 Skyline Drive, Hawthorne, New York, 10532. Taro Canada is a wholly-owned subsidiary of Taro Israel and acts at the direction of, under the control of, and for the benefit of Taro Israel.

6. Taro Pharmaceutical Industries Ltd. ("Taro Israel") is an Israeli company with its principal place of business at 14 Hakitor Street, Haifa Bay, 2624761 Haifa, Israel. Taro Israel may be served with process by and through its agent in the United States, Taro USA, at 3 Skyline Drive, Hawthorne, New York, 10532.

7. Taro USA, Taro Canada, and Taro 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. 209148 (the "ANDA").

JURISDICTION AND VENUE

8. This is a complaint for patent infringement. This Court has jurisdiction over the subject matter of the claims asserted pursuant to 28 U.S.C. §§ 1331 and 1338(a). Venue in this Court is proper under 28 U.S.C. §§ 1391 and 1400(b).

9. This Court has personal jurisdiction over Taro USA, Taro Canada, and Taro Israel (collectively, "Taro") because these entities collaborate to manufacture, import, offer for sale, sell, and/or distribute pharmaceutical products throughout the United States, including this judicial district, pursuant to FDA approval of various ANDAs, including the ANDA at issue here.

10. Taro USA regularly acts as Taro Israel's U.S. agent for filings with the FDA, including the ANDA at issue here. Taro USA, Taro Canada, and Taro Israel operate as an integrated business, as evidenced by Taro Israel's 2016 Form 20-F, which indicates that Taro

Israel files a single annual report to the U.S. Securities and Exchange Commission for itself and its subsidiaries: Taro USA and Taro Canada.

11. Lab batches to support the ANDA were manufactured by Taro Canada and, following approval, Taro Canada will manufacture commercial quantities of the Accused Product described in the ANDA for importation, offer for sale, sale, and/or distribution by Taro USA throughout the United States, including this judicial district.

12. Taro 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.—a company located in this district—would be injured by such actions in this district, and delivered its Paragraph IV Certification to Galderma L.P. in this district. Taro intends to sell the infringing product in or for distribution in this district upon approval by the FDA. Taro has thus purposefully targeted its conduct to cause harm in the State of Texas, and particularly in this district.

13. Venue is proper in this district because the claims asserted herein arise out of an act of patent infringement—Taro's submission of the ANDA and issuance of the Paragraph IV Certification—purposefully targeting a resident of this district, 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 Taro could file suit seeking a declaration of non-infringement in connection with the ANDA.

BACKGROUND FACTS

A. The '543 Patent

14. 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.

15. The ʻ543 Patent is valid, enforceable, and has not expired.

B. The ʻ420 Patent

16. On July 22, 2014, the USPTO issued the ʻ420 Patent, entitled "Combination/Association of Adapalene and Benzoyl Peroxide for Treating Acne Lesions," to Galderma R&D.

17. The ʻ420 Patent is valid, enforceable, and has not expired.

C. The ʻ305 Patent

18. On August 19, 2014, the USPTO issued the ʻ305 Patent, entitled "Administration of Adapalene and Benzoyl Peroxide for the Long-Term Treatment of Acne Vulgaris," to Galderma R&D.

19. The ʻ305 Patent is valid, enforceable, and has not expired.

D. Epiduo® Forte Gel

20. Galderma L.P. is the owner of New Drug Application ("NDA") No. 207917. On July 15, 2015, Galderma L.P. obtained FDA Approval to market Epiduo® Forte Gel. The ʻ543 Patent, ʻ420 Patent, and ʻ305 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%.

21. Galderma S.A. and Galderma R&D have granted Galderma L.P. the exclusive right to sell and offer for sale Epiduo® Forte Gel in the United States.

E. Taroʻs Infringement

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

23. Prior to June 17, 2016, Taro decided to file an application seeking FDA approval to sell a generic version of Epiduo® Forte Gel.

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

25. Taro submitted Abbreviated New Drug Application No. 209148 (the "ANDA") 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.

26. 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.

27. On or about June 17, 2016, Taro sent a letter (the "Certification Letter") to Galderma L.P. in Fort Worth, Texas and to Galderma R&D and Galderma S.A. Through the Certification Letter, Taro first notified Plaintiffs that Taro 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 Taroʹs 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.

28. Taro was aware of the ʹ543 Patent, ʹ420 Patent, and ʹ305 Patent when it filed the ANDA and/or sent the Certification Letter.

29. Plaintiffs have commenced this action within 45 days of the date that they received the Certification Letter.

30. Taro 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

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

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

33. 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), Taro 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.

34. Taro 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.

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

36. Taro intends that physicians will prescribe, and patients will use, the Accused Product in accordance with the indication(s) sought by Taro and will therefore infringe one or more claims of the ʹ543 Patent under 35 U.S.C. § 271(b).

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

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

39. As a result of Taroʹs infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the ʹ543 Patent if made, used as directed, sold, offered for sale, or imported during the term of the ʹ543 Patent.

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

41. As a result of Taroʹs infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Taro and all those in privity with or acting in concert with Taro from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the ʹ543 Patent, or from otherwise infringing or inducing the infringement of the ʹ543 Patent.

COUNT II:
INFRINGEMENT OF U.S. PATENT NO. 8,785,420

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

43. The ʹ420 Patent is valid, enforceable, and has not expired.

44. The Accused Product and/or its use as directed infringes one or more claims of the ʹ420 Patent. As such, under 35 U.S.C. § 271(e)(2)(A), Taro infringed the ʹ420 Patent by

submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the ʹ420 Patent,

45. Taro will induce infringement of one or more claims of the ʹ420 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 ʹ420 Patent by users of the Accused Product.

46. Taro seeks approval of at least one indication for the Accused Product that is claimed in the ʹ420 Patent.

47. Taro intends that physicians will prescribe, and patients will use, the Accused Product in accordance with the indication(s) sought by Taro and will therefore infringe one or more claims of the ʹ420 Patent under 35 U.S.C. § 271(b).

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

49. As such, under 35 U.S.C. § 271(e)(2)(A), Taro has infringed the ʹ420 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the ʹ420 Patent.

50. As a result of Taroʹs infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the ʹ420 Patent if made, used as directed, sold, offered for sale, or imported during the term of the ʹ420 Patent.

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

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

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

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

55. Use of the Accused Product will infringe one or more claims of the '305 Patent. Under 35 U.S.C. § 271(e)(2)(A), Taro 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.

56. Taro 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).

57. Taro 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.

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

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

60. As a result of Taroˈs 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.

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

62. As a result of Taroˈs infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Taro and all those in privity with or acting in concert with Taro 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 Taro 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 Taro'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 '543 Patent, '420 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 Taro has infringed the '543 Patent, '420 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 '543 Patent, '420 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 Taro 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 '543

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 Taroʹs 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: July 29 , 2016

Respectfully submitted,

/s/ Jamil N. Alibhai

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