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. _____**
v.	§	
TOLMAR INC.	§	
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 TOLMAR INC. and state 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 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 Research & Development, S.N.C. ("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 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. Tolmar Inc. ("Tolmar") is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 3 Skyline Drive, Hawthorne, New York, 10532. Tolmar may be served with process by and through its registered agent for service of process, Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware, 19808.

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 Tolmar because Tolmar sells products for distribution throughout the United States and regularly conducts business in the State of

Texas. Tolmar 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. Tolmar intends to sell the infringing product in or for distribution in this district upon approval by the FDA. Tolmar 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.*, Tolmar'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 Tolmar could file suit seeking a declaration of non-infringement in connection with the ANDA.

BACKGROUND FACTS

A. The '644 Patent

8. 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.

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

B. The '537 Patent

10. 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.

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

C. The ˈ362 Patent

12. On March 6, 2012, the USPTO issued the ˈ362 Patent, entitled "Combination/ Association of Adapalene and Benzoyl Peroxide for Treating Acne Lesions," to Galderma R&D.

13. The ˈ362 Patent is valid, enforceable, and has not expired.

D. The ˈ543 Patent

14. On May 21, 2013, the USPTO issued the ˈ543 Patent, entitled "Combinations of Adapalene and Benzoyl Peroxide for Treating Acne Lesions," to Galderma R&D.

15. The ˈ543 Patent is valid, enforceable, and has not expired.

E. The ˈ305 Patent

16. 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 Galderma R&D.

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

F. Epiduo® Gel

18. 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 ˈ644 Patent, ˈ537 Patent, ˈ362 Patent, ˈ543 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® (adapalene and benzoyl peroxide) Gel, 0.1% / 2.5%.

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

G. Tolmar's Infringement

20. Tolmar is in the business of developing, manufacturing, and marketing generic pharmaceutical products.

21. Prior to March 8, 2016, Tolmar decided to file an application seeking FDA approval to sell a generic version of Epiduo® Gel.

22. During the process of preparing such application, Tolmar reviewed the '644 Patent, '537 Patent, '362 Patent, '543 Patent, and '305 Patent and certain commercial and economic information relating to Epiduo® Gel.

23. Tolmar submitted Abbreviated New Drug Application No. 206164 (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 '644 Patent, '537 Patent, '362 Patent, '543 Patent, and '305 Patent.

24. The Accused Product and its use will directly and indirectly infringe one or more claims of the '644 Patent, '537 Patent, '362 Patent, '543 Patent, and '305 Patent.

25. On or about March 8, 2016, Tolmar 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, Tolmar first notified Plaintiffs that Tolmar 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 Tolmar's opinion, the claims of the '644 Patent, '537 Patent, '362 Patent, '543 Patent, and '305 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.

26. Tolmar 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.

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

28. Tolmar 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

29. Plaintiffs incorporate paragraphs 1 through 28 above by reference as if fully set forth herein.

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

31. The Accused Product and/or its use infringes one or more of the claims of the ʹ644 Patent. As such, under 35 U.S.C. § 271(e)(2)(A), Tolmar 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.

32. Tolmar 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.

33. Tolmar seeks approval of at least one indication for the Accused Product that is claimed in the ʹ644 Patent.

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

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

36. As a result of Tolmarʹs 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.

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

38. Plaintiffs incorporate paragraphs 1 through 37 above by reference as if fully set forth herein.

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

40. The Accused Product and/or its use as directed infringes one or more of the claims of the ʹ537 Patent. As such, under 35 U.S.C. § 271(e)(2)(A), Tolmar 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.

41. Tolmar will induce infringement of one or more claims of the ˈ537 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 ˈ537 Patent by users of the Accused Product.

42. Tolmar seeks approval of at least one indication for the Accused Product that is claimed in the ˈ537 Patent.

43. Tolmar knows that physicians will prescribe, and patients will use, the Accused Product in accordance with the indication(s) sought by Tolmar and will therefore infringe one or more claims of the ˈ537 Patent under 35 U.S.C. § 271(b).

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

45. As a result of Tolmarˈs infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the ˈ537 Patent if made, used as directed, sold, offered for sale, or imported during the term of the ˈ537 Patent.

46. As a result of Tolmarˈs infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Tolmar and all those in privity with or acting in concert with Tolmar from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the ˈ537 Patent, or from otherwise infringing or inducing the infringement of the ˈ537 Patent.

COUNT III:
INFRINGEMENT OF U.S. PATENT NO. 8,129,362

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

48. The ˈ362 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 ˈ362 Patent. As such, under 35 U.S.C. § 271(e)(2)(A), Tolmar infringed the ˈ362 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the ˈ362 Patent.

50. Tolmar will induce infringement of one or more claims of the ˈ362 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 ˈ362 Patent by users of the Accused Product.

51. Tolmar seeks approval of at least one indication for the Accused Product that is claimed in the ˈ362 Patent.

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

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

54. As a result of Tolmarˈs 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.

55. As a result of Tolmar's infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Tolmar and all those in privity with or acting in concert with Tolmar from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the '362 Patent, or from otherwise infringing or inducing the infringement of the '362 Patent.

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

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

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

58. The Accused Product and/or its use as directed infringes one or more of the claims of the '543 Patent. As such, under 35 U.S.C. § 271(e)(2)(A), Tolmar 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.

59. Tolmar 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.

60. Tolmar seeks approval of at least one indication for the Accused Product that is claimed in the '543 Patent.

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

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

63. As a result of Tolmar'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.

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

65. Plaintiffs incorporate paragraphs 1 through 64 above by reference as if fully set forth herein.

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

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

68. Tolmar 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).

69. Tolmar 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 ˈ305 Patent by users of the Accused Product.

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

71. As a result of Tolmarˈs 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.

72. As a result of Tolmarˈs infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Tolmar and all those in privity with or acting in concert with Tolmar 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 Tolmar 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 Tolmarˈs 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 ˈ644 Patent, ˈ537 Patent, ˈ362 Patent, ˈ543 Patent, and ˈ305 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 Tolmar 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 Tolmar 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 Tolmar'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

Michael C. Wilson
Texas State Bar No. 21704590
mwilson@munckwilson.com
Jamil N. Alibhai
Texas State Bar No. 00793248
jalibhai@munckwilson.com
Daniel E. Venglarik
Texas 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
600 Banner Place Tower
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 GALDERMA RESEARCH & DEVELOPMENT, S.N.C.

688800.