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.	§	
WATSON PHARMACEUTICALS, INC. and WATSON LABORATORIES, INC.	§	
Defendants.	§	

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 Defendants WATSON PHARMACEUTICALS, INC. and WATSON LABORATORIES, INC. 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 U.S. Food and Drug Administration ("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 2, 1018 Lausanne, Switzerland. Galderma S.A. is involved in the research, development, marketing, and/or 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"), and U.S. Patent No. 8,129,362 (the "'362 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."

4. Watson Pharmaceuticals, Inc. ("Watson") is a Nevada corporation with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. Watson develops, manufactures, and markets generic versions of branded pharmaceutical products through various operating subsidiaries, including Defendant Watson Laboratories, Inc. Watson may be served with process by and through its registered agent for service of process, CT Corporation System, 818 West Seventh Street, Los Angeles, California 90017.

5. Watson Laboratories, Inc. ("Watson Labs") is a Nevada corporation with its principal place of business at 311 Bonnie Circle, Corona, California 92880. Watson Labs is a wholly-owned subsidiary of Watson Pharmaceuticals, Inc. On information and belief, Watson Labs is in the business of, among other things, developing, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. Market. Watson Labs may be served

with process by and through its registered agent for service of process, CT Corporation System, 818 West Seventh Street, Los Angeles, California 90017.

6. Watson and Watson Labs have common officers and directors. On information and belief, Watson directed, authorized, participated in, assisted, and cooperated with Watson Labs in all of the acts complained of herein. On information and belief, Watson Labs is the alter-ego of Watson and/or is controlled by and/or is an agent of Watson with respect to acts complained of herein. Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. are collectively referred to herein as "Defendants."

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 Defendants because Defendants manufacture and/or sell products for distribution throughout the United States and, on information and belief, regularly conduct business in the State of Texas. On information and belief, Watson and Watson Labs acted in concert to prepare and submit Abbreviated New Drug Application No. 204067 (the "ANDA") to the FDA (an act of infringement under 35 U.S.C. § 271(e)(2)), including a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (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.

9. Defendants submitted the ANDA seeking approval from the FDA 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, *inter alia,* the '644 Patent, '537 Patent,

and '362 Patent. Upon information and belief, Watson and Watson Labs actively participated in the development of the Accused Product and/or preparation of the ANDA, and submitted the ANDA to the FDA. Upon information and belief, Watson Labs acted as the agent of Watson in submitting the ANDA to the FDA.

10. On or about June 15, 2012, Watson Labs sent a letter (the "Notice of Paragraph IV Certification Letter") pursuant to 21 U.S.C. § 355(j)(2)(B) to Galderma L.P. in Fort Worth, Texas, and to Galderma R&D in France. Through the Notice of Paragraph IV Certification Letter, Defendants first notified Galderma L.P. and Galderma R&D that Watson Labs had filed the ANDA with the FDA relating to the Accused Product and that the ANDA includes a Paragraph IV Certification that, in Watson Labs' opinion, the claims of the '644 Patent, '537 Patent, and '362 Patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the Accused Product before the expiration date of such patents.

11. On information and belief, Defendants intend to sell the Accused Product in, or for distribution in, this district upon approval by the FDA. Defendants thus purposefully targeted its conduct to cause harm in the State of Texas and this district. Watson also is subject to jurisdiction in Texas on the basis of its inducement of and/or contribution to Watson Labs' acts of infringement in Texas. In addition, Watson is subject to personal jurisdiction in Texas because, on information and belief, it controls Watson Labs; therefore, the activities of Watson Labs in this district are attributed to Watson.

12. Venue is proper in this district because the claims asserted herein arise out of an act of patent infringement (*i.e.*, the submission of the ANDA and delivery of the Notice of Paragraph IV Certification Letter) 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 Defendants could file suit seeking a declaration of non-infringement in connection with the ANDA.

BACKGROUND FACTS

A. The '644 Patent

13. On December 6, 2011, the United States Patent and Trademark Office ("USPTO") issued the '644 Patent, entitled "Combinations of Adapalene and Benzoyl Peroxide for Treating Acne Lesions," to Galderma R&D.

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

B. The '537 Patent

15. 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.

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

C. The '362 Patent

17. 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.

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

D. Epiduo® Gel

19. 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 '644 Patent, '537 Patent, and '362 Patent are listed in the FDA publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the "Orange Book") in

association with Epiduo® (adapalene and benzoyl peroxide) Gel, 0.1% / 2.5% and cover FDA approved use of Epiduo® Gel for the treatment of acne.

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

E. Watson's Infringement

21. Defendants are in the business of developing, manufacturing, and/or marketing generic versions of branded pharmaceutical products.

22. On information and belief, Defendants reviewed the '644 Patent, '537 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.

23. Watson and Watson Labs acted in concert to prepare and submit to the FDA the ANDA and Paragraph IV Certification. Submitting the ANDA is an act of infringement under 35 U.S.C. § 271(e)(2).

24. Defendants were aware of the '644 Patent, '537 Patent, and '362 Patent when Watson Labs filed the ANDA and/or sent the Notice of Paragraph IV Certification Letter.

25. Making, using, offering to sell, selling, or importing the Accused Product that is the subject of the ANDA directly and indirectly infringes one or more claims of the '644 Patent, '537 Patent, and '362 Patent, either literally or under the doctrine of equivalents.

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

27. On information and belief, Defendants intend 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

28. Plaintiffs incorporate paragraphs 1 through 27 above by reference as if fully set forth herein.

29. The '644 Patent is valid, enforceable, and has not expired. The approved use of Epiduo® Gel is covered by one or more claims of the '644 patent.

30. Upon information and belief, the use of the Accused Product in accordance with and as directed by Defendants' proposed product labeling would infringe one or more of the claims of the '644 Patent, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Defendants infringed the '644 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '644 Patent.

31. Upon information and belief, Defendants will induce infringement of one or more claims of the '644 Patent—in violation of Plaintiffs' patent rights—if the FDA approves the sale of the Accused Product with Defendants' proposed product labeling regarding the indication(s) and/or use of the Accused Product.

32. On information and belief, Defendants seek approval of at least one indication for the Accused Product that is claimed in the '644 Patent.

33. On information and belief, Defendants know that physicians will prescribe, and patients will use, the Accused Product in accordance with the indication(s) sought by Defendants and will therefore infringe one or more claims of the '644 Patent under 35 U.S.C. § 271(b).

34. Upon information and belief, Defendants know that the Accused Product and its product labeling are especially made or adapted for use that infringes the '644 patent, the Accused Product is not a staple article or commodity of commerce, and that the Accused Product and its product labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '644 patent upon approval of the ANDA by the FDA.

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

36. As a result of Defendants' infringement, Plaintiffs are entitled to a declaration that Defendants infringe the '644 Patent if the Accused Product is made, used as directed, sold, offered for sale, or imported during the term of the '644 Patent.

37. As a result of Defendants' infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Defendants and all those in privity with or acting in concert with Defendants from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the '644 Patent, or from otherwise infringing, inducing the infringement, and/or contributing to the infringement of the '644 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 '537 Patent is valid, enforceable, and has not expired. The approved use of Epiduo® Gel is covered by one or more claims of the '537 Patent.

40. Upon information and belief, the use of the Accused Product in accordance with and as directed by Defendants' proposed product labeling would infringe one or more of the claims of the '537 Patent, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Defendants 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.

41. Upon information and belief, Defendants will induce infringement of one or more claims of the '644 Patent—in violation of Plaintiffs' patent rights—if the FDA approves the sale of the Accused Product with Defendants' proposed product labeling regarding the indication(s) and/or use of the Accused Product.

42. On information and belief, Defendants seek approval of at least one indication for the Accused Product that is claimed in the '537 Patent.

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

44. Upon information and belief, Defendants know that the Accused Product and its product labeling are especially made or adapted for use that infringes the '537 Patent, the Accused Product is not a staple article or commodity of commerce, and that the Accused Product and its product labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '537 Patent upon approval of the ANDA by the FDA.

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

46. As a result of Defendants' infringement, Plaintiffs are entitled to a declaration that Defendants infringe the '537 Patent if the Accused Product is made, used as directed, sold, offered for sale, or imported during the term of the '537 Patent.

47. As a result of Defendants' infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Defendants and all those in privity with or acting in concert with Defendants from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the '537 Patent, or from otherwise infringing, inducing the infringement, and/or contributing to 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. The approved use of Epiduo® Gel is covered by one or more claims of the '362 Patent.

50. Upon information and belief, the use of the Accused Product in accordance with and as directed by Defendants' proposed product labeling would infringe 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), Defendants 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, Defendants 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 Defendants' proposed product labeling regarding the indication(s) and/or use of the Accused Product.

52. On information and belief, Defendants seek approval of at least one indication for the Accused Product that is claimed in the '362 Patent.

53. Upon information and belief, Defendants will induce infringement of one or more claims of the '644 Patent—in violation of Plaintiffs' patent rights—if the FDA approves the sale of the Accused Product with Defendants' proposed product labeling regarding the indication(s) and/or use of the Accused Product.

54. Upon information and belief, Defendants know that the Accused Product and its product labeling are especially made or adapted for use that infringes the '362 Patent, the Accused Product is not a staple article or commodity of commerce, and that the Accused Product and its product labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '362 Patent upon approval of the ANDA by the FDA.

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

56. As a result of Defendants' infringement, Plaintiffs are entitled to a declaration that Defendants infringe the '362 Patent if the Accused Product is made, used as directed, sold, offered for sale, or imported during the term of the '362 Patent.

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

DEMAND FOR JURY TRIAL

Plaintiffs demand trial by jury of all issues and claims so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for the following relief:

(A) A declaration that Defendants' commercial manufacture, use, offer for sale, 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, 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 Defendants have infringed the '644 Patent, '537 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 '644 Patent, '537 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 Defendants 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, inducing the infringement, and/or contributing to the infringement of the '644 Patent, '537 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 Defendants' 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, 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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