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U.S. DISTRICT COURT
NORTHERN DIST. OF TX.
FORT WORTH DIVISION
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CLERK OF COURT

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

GALDERMA LABORATORIES, L.P.
and GALDERMA S.A.,
Plaintiffs,

v.

ACTAVIS MID-ATLANTIC, L.L.C.,
Defendant

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4-08CV-115-A
CIVIL ACTION NO. _____

Jury Trial Requested

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, GALDERMA LABORATORIES, L.P. ("Galderma L.P.") and GALDERMA S.A. ("Galderma S.A."), file this Complaint For Patent Infringement against Defendant, ACTAVIS MID-ATLANTIC, L.L.C. ("Actavis"), and state:

INTRODUCTION

1. This is a civil action for patent infringement in violation of the United States Patent Act, 35 U.S.C. § 271, et seq.

2. This suit stems from Actavis's filing of an Abbreviated New Drug Application, including any amendments ("the ANDA") with the United States Food and Drug Administration (the "FDA") pursuant to 21 U.S.C. § 355.

PARTIES

3. Galderma L.P. is a Texas limited partnership, with its principal business address at 14501 N. Freeway, Fort Worth, Texas 76177. Galderma L.P. is the beneficial holder of rights to market CLOBEX[®] Shampoo (clobetasol propionate shampoo (0.05%)) (hereafter "Clobex[®] Shampoo") under FDA approval of New Drug Application No. 21-644. Galderma L.P. has the exclusive right from Galderma S.A. to distribute Clobex[®] Shampoo in the United States.

4. Galderma S.A. is a Swiss corporation, with its principal business address at World Trade Center, Avenue de Gratta-Paille, Case Postale 453, CH-Lausanne 30, Switzerland. Galderma S.A. owns United States Patent No. 7,316,810 (the “810 Patent”). A copy of the ‘810 Patent is attached as Exhibit “A.”

5. Actavis is a Delaware limited liability company, with its principal place of business at 200 Elmora Ave., Elizabeth, New Jersey 07207. On or about January 8, 2008, Actavis mailed a notice-of-certification letter (the “Certification Letter”) to Galderma L.P. in Fort Worth, Texas, and to Galderma S.A. in Switzerland. Pursuant to the Certification Letter, Actavis has agreed that it may be served with process by and through its authorized agent for service of process, Edgar H. Haug, Esq., Frommer Lawrence & Haug LLP, 745 Fifth Avenue, New York, New York 10151.

JURISDICTION AND VENUE

6. This is a complaint for patent infringement and for declaratory judgment of patent infringement. This Court has jurisdiction over the subject matter of the claims asserted pursuant to 28 U.S.C. §§ 1331 and 1338, as well as 28 U.S.C. §§ 2201 and 2202. Venue in this Court is proper under 28 U.S.C. §§ 1391 and 1400(b).

7. This Court has personal jurisdiction over Actavis in that Actavis manufactures and/or sells products for distribution throughout the United States and, on information and belief, regularly conducts business in the State of Texas. Actavis also filed the ANDA 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, Actavis intends to sell the

infringing product in or for distribution to this district upon approval by the FDA. Actavis has thus purposefully targeted its conduct to cause harm in the State of Texas and this district.

8. Venue is appropriate in this district because the claims asserted herein arise out of an act of patent infringement (i.e., Actavis's filing of the ANDA and issuance of the Paragraph IV Certification) purposefully targeting a resident of this district (i.e., Galderma L.P.). Further, 21 U.S.C. § 355(j)(5)(C)(i)(II) establishes this district as the only proper venue in which Actavis could file suit seeking a declaration of non-infringement in connection with the ANDA. In addition, Actavis has consented to venue in this district in a related case involving a Clobex[®] product, styled *Galderma Laboratories, L.P. and Galderma S.A. v. Actavis Mid-Atlantic, L.L.C.*, Civil Action No. 4:06-CV-471-Y.

BACKGROUND FACTS

A. The '810 Patent

9. On November 13, 2000, Isabelle Preuilh, Anne-Emmanuelle Guise, and Nathalie Willcox (inventors) and Galderma S.A. (assignee) filed an application with the United States Patent and Trademark Office ("USPTO"), namely United States Patent Application Serial No. 09/709,477 (the "'477 Application") entitled "Foaming Composition For Washing and Treating Hair and/or Scalp Based on an Active Principle." On January 8, 2008, based on the '477 Application, the USPTO issued the '810 Patent.

10. The '810 Patent is directed to certain compositions and claims:

A foaming composition for washing and treating the hair and/or the scalp consisting of 0.24 g citric acid, 2.6 g sodium citrate, 2 g polyquaternium 10, 17 g of sodium lauryl ether sulphate (2 moles of ethylene oxide, comprising 70% of active material), 6 g of cocoyl betaine (comprising 32% active material), 0.05 g clobetasol propionate, 10 g ethanol (95/96%), and q.s. for 100 g purified water.

'810 Patent at 16:39-45.

11. The '810 Patent is valid, enforceable, and has not expired.

12. Isabelle Preuilh, Anne-Emmanuelle Guise, and Nathalie Willcox assigned their rights to and interest in the '477 Application and the '810 Patent to Galderma S.A.

13. On February 5, 2004, Galderma L.P. obtained FDA approval to market Clobex[®] Shampoo. The '810 Patent is listed in the FDA's Approved Drug Products list (the "Orange Book") as reading on Clobex[®] Shampoo.

14. Galderma S.A. has granted Galderma L.P. the exclusive right to distribute Clobex[®] Shampoo in the United States.

B. Actavis' Infringement

15. Upon information and belief, Actavis is in the business of developing, manufacturing, and marketing generic pharmaceutical products.

16. On or about March 30, 2007, Actavis filed ANDA No. 78-854 for clobetasol propionate shampoo 0.05% (the "Accused Product"). Pursuant to the ANDA, Actavis seeks permission from the FDA to market and sell the Accused Product in the United States.

17. On or about January 8, 2008, Actavis mailed the Certification Letter to Galderma L.P. in Fort Worth, Texas, and to Galderma S.A. in Switzerland. Through the Certification Letter, Actavis first notified Plaintiffs that Actavis had filed the ANDA and an amended ANDA with the FDA relating to the Accused Product.

18. In the Certification Letter and in the amended ANDA, Actavis contends that the '810 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Accused Product. Plaintiffs dispute this contention.

19. Plaintiffs are filing this Complaint within forty-five (45) days of receipt of the Certification Letter.

COUNT I
(PATENT INFRINGEMENT)

20. Plaintiffs incorporate paragraphs 1 through 19 above by reference as if fully set forth herein.

21. 35 U.S.C. § 271(e)(2)(A) provides:

It shall be an act of infringement to submit . . . an application under section 355(j) of title 21 or described in section 355(b)(2) of title 21 for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

22. The '810 Patent is valid, enforceable, and has not expired. Also, the Accused Product falls within the literal scope of the claims of the '810 Patent and/or infringes the '810 Patent under the doctrine of equivalents. As such, Actavis infringed the '810 Patent by filing the ANDA and/or amended ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '810 Patent.

23. As a result of Actavis's infringement, Plaintiffs are entitled to a declaration that (a) the '810 Patent is valid and enforceable, and (b) the Accused Product infringes the '810 Patent if made, used, sold or offered for sale during the term of the '810 Patent.

24. As a result of Actavis's infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Actavis and all those in privity with or acting in concert with Actavis from manufacturing, selling, or offering the Accused Product for sale during the term of the '810 Patent, or from otherwise infringing or inducing the infringement of the '810 Patent.

DEMAND FOR JURY TRIAL

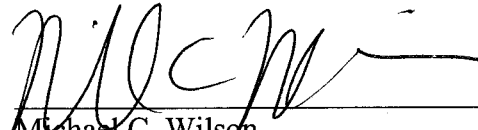
Plaintiffs hereby demand trial by jury of all issues and claims alleged herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs hereby pray for the following relief:

- (A) A declaration that the '810 Patent is valid and enforceable;
- (B) A declaration, pursuant to 35 U.S.C. § 271(e), that Actavis has infringed the '810 Patent by filing the ANDA;
- (C) A declaration, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of the ANDA is not to be earlier than the expiration date of the '810 Patent;
- (D) A permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 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 manufacturing, selling, or offering the Accused Product for sale, or from otherwise infringing or inducing the infringement of the '810 Patent;
- (E) An award to Plaintiffs, pursuant to 35 U.S.C. § 271(e)(4)(C), of damages and other monetary relief, including enhanced damages, as a result of Actavis' 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 expiration of the '810 Patent;
- (F) A declaration that this is an exceptional case and an award, pursuant to 35 U.S.C. §§ 271(e)(4) and 285, granting Plaintiffs their costs and attorneys' fees in pursuing this case; and
- (G) Such other and further relief as this Court may deem just and proper.

Respectfully submitted,



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