IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

GALDERMA LABORATORIES, L.P. and GALDERMA S.A.,	§	
	§	
Plaintiffs,	§	
	§	
v.	§	**CIVIL ACTION NO. _____**
	§	
TELIGENT, INC. f/k/a IGI LABORATORIES, INC.,	§	
	§	
Defendant.	§	

ORIGINAL COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, GALDERMA LABORATORIES, L.P. and GALDERMA S.A. file this Original Complaint for Patent Infringement against Defendant TELIGENT, INC. F/K/A IGI LABORATORIES, INC.:

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 Clobex® (clobetasol propionate) Lotion, 0.05% ("Clobex® Lotion") under FDA approval of New Drug Application No. 021535, approved July 24, 2003. Galderma L.P. has an exclusive license from Galderma S.A. to distribute Clobex® Lotion in the United States. Clobex® Lotion is a topical prescription drug for the treatment of steroid responsive dermatoses (eczema, dermatitis).

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. Galderma S.A. owns United States Patent No. 6,106,848 (the "'848 Patent"). A copy of the '848 Patent is attached as Exhibit A.

3. Teligent Inc. f/k/a IGI Laboratories, Inc. ("IGI") is a Delaware corporation with its principal place of business at 105 Lincoln Avenue, Buena, New Jersey 08310. IGI may be served with process through its authorized agent at Merchant & Gould P.C., 10 E. Doty Street, Suite 600, Madison, WI 53703-3376.

4. IGI Laboratories, Inc. changed its name to Teligent, Inc., effective October 23, 2015.

5. Defendant IGI submitted to the United States Food and Drug Administration ("FDA"), pursuant to 21 U.S.C. § 355(j) (Section 505(j) of the Federal Food, Drug and Cosmetic Act), Abbreviated New Drug Application ("ANDA") No. 208667 seeking approval to engage in the commercial manufacture, use, and sale of generic clobetasol propionate lotion 0.05% (the "Accused Product").

JURISDICTION AND VENUE

6. 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).

7. This Court has personal jurisdiction over IGI because IGI sells products for distribution throughout the United States and, on information and belief, regularly conducts business in the State of Texas. IGI 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. Moreover, on

information and belief, IGI intends to sell the infringing product in or for distribution in this district upon approval by the FDA. IGI has thus purposefully targeted its conduct to cause harm in the State of Texas and this district.

8. Venue is proper in this district because the claims asserted herein arise out of an act of patent infringement (*i.e.*, IGI'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 IGI could file suit seeking a declaration of non-infringement in connection with the ANDA.

BACKGROUND FACTS

A. The ˈ848 Patent

9. On August 22, 2000, the United States Patent and Trademark Office ("USPTO") issued the ˈ848 Patent entitled, "Topically Applicable O/W Emulsions Having High Glycol Content and At Least One Biologically Active Agent."

10. The ‘848 Patent is directed to certain emulsions, which are described generally as:

> Stable, topically applicable oil-in-water bioaffecting emulsions having intermediate viscosity, characteristically ranging from 3 to 10 Pa.s, comprise (a) from 30% to 50% by weight of at least one pro-penetrating glycol, (b) at least one emulsifying agent, advantageously an anionic amphiphilic polymer, and (c) at least one biologically active agent, for example an active agent that modulates skin differentiation and/or proliferation and/or pigmentation, an anti-inflammatory, an antibacterial, an antifungal, etc.

ˈ848 Patent at Abstract, p. 1.

11. The ˈ848 Patent is valid, enforceable, and has not expired.

B. Clobex® Lotion

12. Galderma L.P. is the holder of New Drug Application ("NDA") No. 021535. On July 24, 2003, Galderma L.P. obtained FDA Approval to market Clobex® Lotion. The '848 Patent is listed in the FDA publication titled *Approved Drug Products With Therapeutic Equivalence Evaluations* (known as the "Orange Book") as covering Clobex® Lotion.

13. On August 18, 2003, Galderma S.A. granted Galderma L.P. the exclusive right to distribute Clobex® Lotion in the United States.

C. IGI's Infringement

14. IGI is in the business of developing, manufacturing, and marketing generic pharmaceutical products.

15. On information and belief, IGI reviewed the '848 Patent and certain commercial and economic information relating to Clobex® Lotion, including estimates of the revenues generated by the sale of Clobex® Lotion.

16. IGI submitted ANDA No. 208667 seeking approval to engage in the commercial manufacture, use, and sale of generic clobetasol propionate lotion 0.05% prior to the expiration of the '848 Patent.

17. On or about October 20, 2015, IGI sent a letter (the "Certification Letter") to Galderma L.P. in Fort Worth, Texas, and to Galderma S.A. in Switzerland. Through the Certification Letter, IGI first notified Plaintiffs that IGI 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 IGI's opinion, the claims of the '848 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.

18. IGI was aware of the '848 Patent when it filed the ANDA and/or sent the Paragraph IV Certification Letter.

19. After receiving the Paragraph IV Certification, Galderma, L.P. requested and IGI granted Galderma confidential access to portions of the ANDA. The ANDA materials included information regarding the specific proposed formulation of the Accused Product, including identity and amount of each active and inactive ingredient. The ANDA materials also included certain manufacturing and testing data regarding the Accused Product. Based on the ANDA materials and Galderma's knowledge and testing of Clobex® Lotion, the Accused Product directly and indirectly infringes one or more claims of the '848 Patent.

20. Plaintiffs have commenced this action within 45 days of the date that they received IGI's notice of the ANDA containing the Paragraph IV certification.

21. On information and belief, IGI 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. 6,106,848

22. Plaintiffs incorporate the foregoing paragraphs by reference as if fully set forth herein.

23. The '848 Patent is valid, enforceable, and has not expired.

24. The Accused Product and/or its use as directed infringes one or more of the claims of the '848 Patent. The Accused Product meets all elements of one or more claims of the '848 Patent, including: (i) between 30% - 50% glycol; (ii) an emulsifying agent comprising an

anionic amphiphilic polymer; and (iii) an active ingredient. The Accused Product is of intermediate viscosity as set forth in the '848 Patent.

25. In addition, pursuant to the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355 *et seq.*, IGI's ANDA must include information showing that the Accused Product (1) contains the same active ingredient as Clobex® Lotion [21 U.S.C. § 355(j)(2)(A)(ii)(I)]; (2) has the same route of administration, dosage form, and strength as Clobex® Lotion [21 U.S.C. § 355(j)(2)(A)(iii)]; and (3) is bioequivalent and/or has the same therapeutic effect as Clobex® Lotion [21 U.S.C. § 355(j)(2)(A)(iv)].

26. As such, under 35 U.S.C. § 271(e)(2)(A), IGI infringed the '848 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '848 Patent.

27. As a result of IGI's infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the '848 Patent if made, used as directed, sold, offered for sale, or imported during the term of the '848 Patent.

28. As a result of IGI's infringement, pursuant to 35 U.S.C. § 271(e)(4)(A), Plaintiffs are entitled to an order 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 '848 Patent including any patent extensions and any additional periods of exclusivity.

DEMAND FOR JURY TRIAL

In the event IGI 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 IGI'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 '848 Patent including any patent extensions, 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 IGI has infringed the '848 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 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 '848 Patent including any patent extensions and any additional periods of exclusivity;

(D) An award to Plaintiffs, pursuant to 35 U.S.C. § 271(e)(4)(C), of damages and other monetary relief, as a result of IGI'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 '848 Patent, including any patent extensions and any additional periods of exclusivity; and

(E) Such other and further relief as this Court may deem just and proper.

Dated: December 4, 2015

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
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. and GALDERMA S.A.

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