ORIGINAL

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

FORT WORTH DIVISION

GALDERMA LABORATORIES, L.P.,
GALDERMA S.A.,
and
DERMALOGIX PARTNERS, INC.,

Plaintiffs,

v.

PADDOCK LABORATORIES, INC.,

Defendant.

4-09CV-002-Y

Civil Action No. _____

COMPLAINT

Plaintiffs Galderma Laboratories, L.P. and Galderma S.A. (collectively "Galderma"), and Dermalogix Partners, Inc. (collectively, "Plaintiffs"), as and for their Complaint against defendant Paddock Laboratories, Inc. ("Defendant"), allege as follows:

THE PARTIES

1. Plaintiff Galderma Laboratories, L.P. is a Texas Limited Partnership, having a principal place of business at 14501 North Freeway, Fort Worth, Texas 76177. As part of its business, Galderma Laboratories, L.P. is involved in the research, development, marketing, and sale of pharmaceutical products.

2. Plaintiff Galderma S.A. is a Swiss Corporation, having a principal place of business at World Trade Center, Avenue de Gratta-Paille 2, Case Postale 453, CH-1000 Lausanne 30 Grey, Switzerland. As part of its business, Galderma S.A. is involved in the research, development, marketing, and sale of pharmaceutical products.

3. Plaintiff Dermalogix Partners, Inc. ("Dermalogix") is a Maine corporation, having a principal place of business at U.S. Route 1, P.O. Box 1510, Scarborough, Maine 04074-9745. As part of its business, Dermalogix is involved in the research and development of pharmaceutical products.

4. On information and belief, defendant Paddock Laboratories, Inc. ("Paddock") is a Minnesota corporation, having a principal place of business at 3940 Quebec Avenue North, Minneapolis, Minnesota 55427-1244 and is engaged in the development, marketing and sale of pharmaceutical products.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States of America, Title 35, United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. Paddock is subject to personal jurisdiction in this District by virtue of, inter alia, its conduct of business in this District, its purposeful availment of the rights and benefits of Texas law, its substantial and continuing contacts with the State, and its knowledge that a Texas Limited Partnership located in this District would be injured by its actions. Upon information and belief, Defendant Paddock engages in the manufacture and sale of a range of generic pharmaceutical products within the United States generally and the State of Texas specifically, including to Wal-Mart and Walgreens pharmacy stores within the State of Texas. See http://www.paddocklabs.com/company_profile.html.

7. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(c). For example, Plaintiff Galderma Laboratories, L.P. is located in this District, and Galderma's witnesses and documents will be material to this litigation. As another example, venue is

appropriate in this District because the claims asserted herein arise out of an act of patent infringement (*i.e.*, Paddock's filing of the ANDA and issuance of the Paragraph IV Certification) purposefully targeting a resident of this District (Galderma Laboratories, L.P.). As a further example, 21 U.S.C. § 355(j)(5)(C)(i)(II) establishes this District as the only proper venue in which Paddock could file suit seeking a declaration of non-infringement in connection with the ANDA.

FACTS PERTINENT TO ALL CLAIMS FOR RELIEF

8. On October 26, 1999, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 5,972,920 (the "'920 patent"), entitled "Formulation Containing a Carrier, Active Ingredient, and Surfactant for Treating Skin Disorders," to Dermalogix Partners, Inc., the assignee of the named inventor William E. Seidel. Dermalogix is the current assignee of the '920 patent.

9. Plaintiff Dermalogix and its licensee Dow Pharmaceutical Sciences, Inc., granted Plaintiff Galderma an exclusive sublicense to the '920 Patent to make, distribute, market, sell, and use a clobetasol propionate spray for the treatment of skin disorders including psoriasis. Galderma's exclusive license included the right to sublicense. A copy of the '920 Patent is attached hereto as Exhibit A.

10. The '920 Patent is valid, enforceable and has not expired.

11. On October 27, 2005, the United States Food and Drug Administration ("FDA") approved New Drug Application ("NDA") No. 21-835 for clobetasol propionate spray .05% for topical application. Galderma is the holder of NDA No. 21-835 for clobetasol propionate spray .05% for topical application, which Galderma sells under the name Clobex®.

12. The '920 patent is listed in the FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (known as the "Orange Book") as covering Clobex® clobetasol propionate spray .05% for topical application.

13. On information and belief, Defendant Paddock engages in the manufacture and sale of a range of generic pharmaceutical products (including generic drug products manufactured and sold pursuant to an approved abbreviated new drug application) within the United States generally and the State of Texas specifically.

14. On information and belief, Paddock actively reviews pharmaceutical patents and seeks opportunities to challenge those patents.

15. On information and belief, Paddock reviewed the '920 patent and certain commercial and economic information relating to Clobex®, including estimates of the revenues generated by the sale of Clobex®, and decided to file an Abbreviated New Drug Application ("ANDA"), seeking approval to market clobetasol propionate spray 0.05%.

16. On information and belief, Paddock submitted to the FDA ANDA No. 90-898 to seek approval to engage in the commercial manufacture, use, and sale of clobetasol propionate spray 0.05% prior to the expiration of the '920 patent.

17. Plaintiffs received a letter dated November 24, 2008 from Paddock notifying them that Paddock's ANDA No. 90-898 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that, in Paddock's opinion, the '920 patent is invalid or unenforceable.

18. By denying infringement of only certain dependent or narrower claims of the '920 patent, Paddock has implicitly admitted infringement of the remaining claims.

19. On information and belief, Paddock was necessarily aware of the '920 patent when it filed ANDA No. 90-898 and a Paragraph IV certification.

20. Plaintiffs commenced this action within 45 days of the date that they received Paddock's notice of ANDA No. 90-898 containing the Paragraph IV certification.

21. On information and belief, Paddock intends to continue seeking approval of ANDA No. 90-898 from the FDA and to engage in the commercial manufacture, marketing and sale of clobetasol propionate spray 0.05% (including commercial marketing and sale of such a product in the State of Texas) in the event that FDA approves ANDA No. 90-898.

FIRST CLAIM FOR RELIEF
(Infringement of the '920 Patent by Paddock)

22. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 21 hereof, as if fully set forth herein.

23. Through the conduct alleged above, Defendant has infringed, and continues to infringe, one or more claims of the '920 Patent.

24. By filing ANDA No. 90-898 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use, and sale of clobetasol propionate spray 0.05% prior to the expiration of the '920 Patent, Defendant has infringed the '920 Patent under 35 U.S.C. § 271(e)(2).

25. Defendant was aware of the existence of the '920 Patent prior to filing ANDA No. 90-898, but took such action knowing that it would constitute an infringement of the '920 Patent.

26. On information and belief, Defendant acted without a reasonable basis or good faith belief that it would not be liable for infringing the '920 Patent.

27. Defendant's conduct renders this case "exceptional" as described in 35 U.S.C. § 285.

28. Plaintiffs will be irreparably harmed if Defendant is not enjoined from infringing the '920 Patent.

CONTINGENT JURY DEMAND

If Defendant should launch a product during the pendency of this litigation, and Plaintiffs incur damages, then Plaintiffs will demand damages and trial by jury of all issues and claims alleged herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. An order adjudging and decreeing that Defendant has infringed the '920 patent;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of ANDA No. 90-898 be no earlier than the expiration date of the '920 patent, including any extensions;

D. A preliminary and permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Paddock, its officers, agents, attorneys, and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the clobetasol propionate products described in ANDA No. 90-898 or any other ANDA not colorably different from ANDA No. 90-898 until the expiration date of the '920 patent, including any extensions;

E. A declaration that this case is exceptional and an award of attorneys' fees under 35 U.S.C. § 285 and costs and expenses in this action;

F. 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 Paddock'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 clobetasol propionate spray 0.05% described in ANDA No. 90-898 prior to expiration of the '920 Patent; and

G. Such other and further relief as the Court may deem just and proper.

Respectfully submitted,

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