

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

-----	x	Civil Action No.
GALDERMA LABORATORIES, L.P.,	)	
GALDERMA S.A.,	)	
and	)	
DERMALOGIX PARTNERS, INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
PERRIGO CO. and PERRIGO ISRAEL	)	
PHARMACEUTICALS LTD.,	)	
	)	
Defendant.	)	
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**COMPLAINT**

Plaintiffs Galderma Laboratories, L.P. and Galderma S.A. (collectively, "Galderma"), and Dermalogix Partners, Inc. (collectively, "Plaintiffs"), as and for their Complaint against defendants Perrigo Co. and Perrigo Israel Pharmaceuticals Ltd. (collectively, "Defendants"), 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 Perrigo Co. ("Perrigo Co.") is a Michigan corporation, having a principal place of business located at 515 Eastern Avenue, Allegan, Michigan 49010, and is engaged in the manufacture and sale of pharmaceutical products.

5. On information and belief, Defendant Perrigo Israel Pharmaceuticals Ltd. ("Perrigo Israel") is an Israeli corporation, having a principal place of business located at 29 Lehi Street, Bnei Brak 51200, Israel. On information and belief, Perrigo Israel manufactures bulk pharmaceutical products.

6. On information and belief, Perrigo Israel is a wholly-owned subsidiary of Perrigo Co.

7. On information and belief, Perrigo Israel is controlled by and/or is an agent of Perrigo Co.

8. On information and belief, Perrigo Israel conducts its North American operations, in part, through Perrigo Co.

#### JURISDICTION AND VENUE

9. 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).

10. Upon information and belief, Defendant Perrigo Co., as reported in its 2009 Annual Report, 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, CVS, Krogers, Safeway, Dollar General, Sam's Club, Costco and Walgreens pharmacy stores within this District.

11. Perrigo Co. 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.

12. Upon information and belief, Defendant Perrigo Israel, as reported in its 2009 Annual Report, engages in the manufacture and sale of a range of generic pharmaceutical products purposefully availed to the United States generally and the State of Texas specifically, including sales to Wal-Mart, CVS, Krogers, Safeway, Dollar General, Sam's Club, Costco and Walgreens pharmacy stores within this District.

13. On information and belief, Perrigo Israel, according to Perrigo Israel's profile in Dun & Bradstreet Israel Ltd., develops and manufactures generic topical drugs for the U.S. market.

14. On information and belief, Perrigo Israel, according to its Corporate Profile, develops and manufactures generic topical drugs at its Yeruham, Israel manufacturing location for the U.S. market as part of the Perrigo Rx Pharmaceuticals Group.

15. On information and belief, generic topical drugs developed and manufactured by Perrigo Israel for the U.S. market includes cetirizine tablets and syrup, clobetasol foam, halobetasol ointment and cream, and mesalamine rectal suspension enema.

16. On information and belief, annual U.S. sales of cetirizine (brand name Zyrtec) tablets and syrup are approximately \$500 million, making it one of the top selling drugs in the United States.

17. On information and belief, Perrigo Israel has approximately 36% of the generic market for cetirizine tablets and syrup.

18. On information and belief, Perrigo Co. acts as an agent of Perrigo Israel with respect to the generic topical drugs developed and manufactured by Perrigo Israel for the U.S. market.

19. On information and belief, Perrigo Israel regularly transacts business within this District, including but not limited to shipping generic pharmaceuticals to Perrigo Co. from locations outside the United States for distribution by Perrigo Co. within the United States generally, and within this District specifically, including among others, generic cetirizine.

20. Perrigo Co.'s acts and contacts with this District, as an agent of Perrigo Israel, are attributable to Perrigo Israel for jurisdictional purposes.

21. Perrigo Israel 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.

22. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(c) and 1400(b). 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., Perrigo Co. and Perrigo Israel'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 Perrigo Co. and Perrigo Israel could file suit seeking a declaration of non-infringement in connection with the ANDA.

FACTS PERTINENT TO ALL CLAIMS FOR RELIEF

23. 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.

24. Plaintiff Dermalogix 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.

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

26. 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®.

27. 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.

28. On information and belief, Defendants 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%.

29. On information and belief, Defendants submitted to the FDA ANDA No. 91-167 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.

30. Plaintiffs received a letter dated October 23, 2009 from Defendants notifying them that Perrigo Co. and Perrigo Israel's ANDA No. 91-167 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that, in Defendants' opinion, the '920 patent is invalid or not-infringed.

31. On information and belief, Defendants were necessarily aware of the '920 patent when they filed ANDA No. 91-167 and a Paragraph IV certification.

32. Plaintiffs commenced this action within 45 days of the date that they received Defendant's notice of ANDA No. 91-167 containing the Paragraph IV certification.

33. On information and belief, Defendants intend to continue seeking approval of ANDA No. 91-167 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, including this District) in the event that FDA approves ANDA No. 91-167.

**FIRST CLAIM FOR RELIEF**  
(Infringement of the '920 Patent by Perrigo Co. and Perrigo Israel)

34. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 33 hereof, as if fully set forth herein.

35. Through the conduct alleged above, Defendants have infringed, and continue to infringe, claims 1-2, 6 and 8-12 of the '920 Patent.

36. By filing ANDA No. 91-167 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, Defendants have infringed the '920 Patent under 35 U.S.C. § 271(e)(2).

37. Defendants were aware of the existence of the '920 Patent prior to filing ANDA No. 91-167, but took such action knowing that it would constitute an infringement of the '920 Patent.

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

39. Defendants' conduct renders this case "exceptional" as described in 35 U.S.C. § 285.

40. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '920 Patent.

#### CONTINGENT JURY DEMAND

If Defendants 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 Defendants have 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. 91-167 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 Perrigo Co. and Perrigo Israel, their officers, agents, attorneys, and employees, and those acting in privity or concert with them, 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. 91-167 or any other ANDA not colorably different from ANDA No. 91-167 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 Perrigo Co. and Perrigo Israel'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. 91-167 prior to expiration of the '920 Patent; and

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



Respectfully submitted,

*/s/ Jamil N. Alibhai*

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