

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

STIEFEL LABORATORIES, INC. and )  
STIEFEL RESEARCH AUSTRALIA PTY. )  
LTD., )  
 )  
Plaintiffs, )  
 )  
v. )  
 )  
PERRIGO ISRAEL PHARMACEUTICALS )  
LTD. and PERRIGO COMPANY, )  
 )  
Defendants. )

C. A. No. \_\_\_\_\_

**COMPLAINT**

Plaintiffs, Stiefel Laboratories, Inc. and Stiefel Research Australia Pty. Ltd. (collectively, “Stiefel”), for their Complaint against Defendants Perrigo Israel Pharmaceuticals Ltd. and Perrigo Company (collectively, “Defendants”), allege as follows:

1. Stiefel Laboratories, Inc. (“Stiefel Laboratories”) is a Delaware corporation having its principal place of business at 20 TW Alexander Drive, PO Box 14910, Research Triangle Park, North Carolina 27709.
2. Stiefel Research Australia Pty. Ltd. (“Stiefel Australia”) is a corporation organized and existing under the laws of the State of Victoria, Australia, having its principal place of business at 8 Macro Court, Rowville, Victoria 3168, Australia. Stiefel Australia is a wholly-owned subsidiary of Stiefel Laboratories.
3. On information and belief, Perrigo Israel Pharmaceuticals Ltd. (“Perrigo Israel”) is an Israeli company with a corporate headquarters and principal place of business at 29 Lehi Street, Bnei Brak 51200, Israel.

4. On information and belief, Perrigo Company (“Perrigo”) is a Michigan corporation having its principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010.

5. On information and belief, Perrigo Israel is a wholly-owned subsidiary of Perrigo and is under the direction, control, and/or influence of Perrigo, both generally and with respect to the particular acts and conduct alleged in this Complaint.

6. On information and belief, Perrigo conducts certain pharmaceutical development and manufacturing operations through Perrigo Israel.

### **JURISDICTION AND VENUE**

7. This is an action for patent infringement arising under the patent laws of the United States.

8. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. Venue in this judicial district is proper pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

10. This Court has personal jurisdiction over Defendants. On information and belief, Defendants manufacture, sell, offer for sale, and cause to be supplied or sold throughout the United States various products, including prescription and over-the-counter pharmaceuticals and nutritional products. Defendants’ products are sold by mass merchandisers, food stores and drug stores throughout the United States, including within this judicial district. On information and belief, Defendants derive substantial revenue from the sales of those products in this district.

11. On information and belief, Defendants have been sued for patent infringement in this judicial district (*see, e.g.*, C.A. Nos. 99-813, 04-107, 09-167, and 09-758), and admitted that they are subject to personal jurisdiction in this Court.

12. Defendants have engaged in substantial and/or continuous and systematic contacts with the State of Delaware, which satisfy due process and confer personal jurisdiction over Defendants.

### **BACKGROUND**

13. Stiefel Laboratories is the owner of an approved New Drug Application under Section 505(b) of the Federal Food Drug and Cosmetic Act (the “FFDCA” or the “Act”), 21 U.S.C. § 355(b)(1), for OLUX-E<sup>®</sup> (clobetasol propionate) Foam, 0.05%.

14. Stiefel Australia is the owner, by assignment, of U.S. Patent Nos. 6,730,288 (“the ‘288 patent”) and 7,029,659 (“the ‘659 patent”). The ‘288 and ‘659 patents are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (“the Orange Book”) for OLUX-E<sup>®</sup>.

15. On information and belief, Perrigo Israel filed with the Food and Drug Administration (“FDA”) Abbreviated New Drug Application (“ANDA”) No. 20-1402 pursuant to § 505(j) of the FFDCA, 21 U.S.C. § 355(j), seeking approval to market a generic version of OLUX-E<sup>®</sup>. Also on information and belief, Perrigo Israel’s ANDA includes a certification pursuant to § 505(j)(2)(A)(vii)(IV) of the Act asserting that the ‘288 and ‘659 patents are invalid, unenforceable, or will not be infringed by the manufacture, use or sale of Defendants’ generic clobetasol propionate emulsion foam 0.05% product (a so-called “Paragraph IV Certification”).

16. On June 1, 2010, Plaintiffs received notice from Perrigo Israel that Perrigo Israel had filed ANDA No. 20-1402 containing a Paragraph IV Certification with respect to the ‘288 and ‘659 patents.

17. On information and belief, Perrigo participated in, contributed to, aided, abetted and/or induced the submission of ANDA No. 20-1402 and its § 505(j)(2)(A)(viii)(IV)

certification to the FDA. On information and belief, Perrigo will be the marketer and seller of the proposed generic product described in ANDA No. 20-1402 if it is approved for sale in the United States.

**COUNT I - INFRINGEMENT OF U.S. PATENT NO. 6,730,288**

18. Plaintiffs incorporate by reference the preceding averments set forth in paragraphs 1 through 17.

19. On May 4, 2004, the '288 patent, entitled "MOUSSE COMPOSITION," was duly and legally issued to Connetics Australia Pty. Ltd. as assignee of the inventors named therein. A true and correct copy of the '288 patent is attached as Exhibit 1.

20. On or about March 26, 2007, Connetics Australia Pty. Ltd. changed its name to Stiefel Research Australia Pty. Ltd. At all relevant times, Stiefel Australia has been and is the assignee and owner of the '288 patent.

21. Perrigo Israel has infringed one or more claims of the '288 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 20-1402 seeking approval to market a generic version of a clobetasol propionate emulsion foam 0.05% prior to the expiration of that patent.

22. Perrigo Israel's manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the clobetasol propionate emulsion foam 0.05% described in ANDA No. 20-1402 would also infringe, directly or indirectly, one or more claims of the '288 patent.

23. Perrigo's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 20-1402 and its Paragraph IV certification to the FDA also constitutes infringement of the '288 patent.

24. On information and belief, unless enjoined, Perrigo will, without authority, manufacture and/or import into the United States Perrigo Israel's generic clobetasol propionate emulsion foam 0.05% described in ANDA No. 20-1402 and/or act as the exclusive distributor of the product within the United States upon Perrigo Israel receiving FDA approval.

25. Perrigo's manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the clobetasol propionate emulsion foam 0.05% described in ANDA No. 20-1402 would infringe, directly or indirectly, one or more claims of the '288 patent.

26. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

27. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4).

28. Defendants were aware of the existence of the '288 patent at the time of the submission of ANDA No. 20-1402 and the § 505(j)(2)(A)(viii)(IV) assertions to the FDA and that that filing constituted infringement of the '288 patent. This is therefore an exceptional case.

**COUNT II - INFRINGEMENT OF U.S. PATENT NO. 7,029,659**

29. Plaintiffs incorporate by reference the preceding averments set forth in paragraphs 1 through 28.

30. On April 18, 2006, the '659 patent, entitled "MOUSSE COMPOSITION," was duly and legally issued to Connetics Australia Pty. Ltd. as assignee of the inventors named therein. A true and correct copy of the '659 patent is attached as Exhibit 2.

31. On or about March 26, 2007, Connetics Australia Pty. Ltd. changed its name to Stiefel Research Australia Pty. Ltd. At all relevant times, Stiefel Australia has been and is the assignee and owner of the '659 patent.

32. Perrigo Israel has infringed one or more claims of the '659 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 20-1402 seeking approval to market a generic version of a clobetasol propionate emulsion foam 0.05% prior to the expiration of that patent.

33. Perrigo Israel's manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the clobetasol propionate emulsion foam 0.05% described in ANDA No. 20-1402 would infringe, directly or indirectly, one or more claims of the '659 patent.

34. Perrigo's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 20-1402 and its Paragraph IV certification to the FDA also constitutes infringement of the '659 patent.

35. Perrigo's manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the clobetasol propionate emulsion foam 0.05% described in ANDA No. 20-1402 will infringe, directly or indirectly, one or more claims of the '659 patent.

36. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

37. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4).

38. Defendants were aware of the existence of the '659 patent at the time of the submission of ANDA No. 20-1402 and the § 505(j)(2)(A)(viii)(IV) assertions to the FDA and that that filing constituted infringement of the '659 patent. This is therefore an exceptional case.

#### **REQUEST FOR RELIEF**

WHEREFORE, Plaintiffs respectfully requests that judgment be entered that:

(a) Defendants have infringed one or more claims of the '288 and '659 patents;

(b) The manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the clobetasol propionate emulsion foam 0.05% described in ANDA No. 20-1402 would infringe one or more claims of the '288 and '659 patents;

(c) The effective date of any approval of ANDA No. 20-1402 for clobetasol propionate emulsion foam 0.05% be no earlier than the expiration dates of the '288 and '659 patents and any additional periods of exclusivity;

(d) Preliminarily and permanently enjoining Defendants, their officers, agents, servants and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Defendants' clobetasol propionate emulsion foam 0.05%;

(e) This is an exceptional case entitling Plaintiffs to an award of its reasonable attorneys' fees, together with interest, and costs of the action, pursuant to 35 U.S.C. § 285; and

(f) Granting such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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