

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

STIEFEL LABORATORIES, INC. and)
STIEFEL RESEARCH AUSTRALIA PTY.)
LTD.,)

Plaintiffs,)

v.)

COBREK PHARMACEUTICALS, INC. 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 Cobrek Pharmaceuticals, Inc. (“Cobrek”) and Perrigo Company (“Perrigo”), allege as follows:

1. Stiefel Laboratories, Inc. (“Stiefel Laboratories”) is a Delaware corporation having its principal place of business at 255 Alhambra Circle, Suite 1000, Coral Gables, Florida 33134.
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, Cobrek is a Delaware corporation having its principal place of business at 2201 West Campbell Park Dr., Suite 26, Chicago, Illinois 60612-4160.

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

JURISDICTION AND VENUE

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

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

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

8. This Court has personal jurisdiction over Cobrek because it is a Delaware corporation.

9. This Court also has personal jurisdiction over Perrigo. On information and belief, Perrigo manufactures, sells, offers for sale, and causes to be supplied or sold throughout the United States various products, including prescription and over-the-counter pharmaceuticals and nutritional products. Perrigo's products are sold by mass merchandisers, food stores and drug stores throughout the United States, including within this judicial district. On information and belief, Perrigo derives substantial revenue from the sales of those products in this district.

10. On information and belief, Perrigo has been sued for patent infringement in this judicial district (C.A. Nos. 99-813 and 04-107), and admitted that it is subject to personal jurisdiction in this Court.

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

BACKGROUND

12. 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 EVOCLIN[®] (clindamycin phosphate) Foam 1%.

13. Stiefel's U.S. Patent Nos. 7,141,237 (the "'237 patent") and 7,374,747 (the "'747 patent") are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for EVOCLIN[®].

14. On information and belief, Cobrek filed with the Food and Drug Administration ("FDA") Abbreviated New Drug Application ("ANDA") No. 90-785 pursuant to § 505(j) of the FFDCA, 21 U.S.C. § 355(j), seeking approval to market a generic version of clindamycin phosphate foam 1%. Also on information and belief, Cobrek's ANDA includes a certification pursuant to § 505(j)(2)(A)(vii)(IV) of the Act asserting that the '237 patent and the '747 patent are invalid, unenforceable, or will not be infringed by the manufacture, use or sale of Cobrek's generic clindamycin phosphate foam 1% product (a so-called "Paragraph IV Certification").

15. On January 29, 2009, Stiefel Laboratories received notice from Cobrek that Cobrek had filed ANDA No. 90-785 containing a Paragraph IV Certification with respect to the '237 and '747 patents. Stiefel Australia received an identical notice from Cobrek on February 2, 2009.

16. On information and belief, Perrigo participated in, contributed to, aided, abetted and/or induced the submission of ANDA No. 90-785 and its § 505(j)(2)(A)(viii)(IV) certification to the FDA.

17. On information and belief, Perrigo and Cobrek have entered into a collaborative agreement to develop and market generic pharmaceutical products for topical use. According to the parties' May 21, 2008 press release, "[t]he parties will share the development costs and profits generated by these products, with Perrigo being the exclusive distributor."

COUNT I - INFRINGEMENT OF U.S. PATENT NO. 7,141,237

18. Stiefel incorporates by reference the preceding averments set forth in paragraphs 1 through 17.

19. On November 28, 2006, the '237 patent, entitled "PHARMACEUTICAL FOAM," was duly and legally issued to Connetics Australia Pty. Ltd. as assignee of the inventors named therein. A true and correct copy of the '237 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 '237 patent.

21. Cobrek has infringed one or more claims of the '237 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-785 seeking approval to market a generic version of a clindamycin phosphate foam 1% prior to the expiration of that patent.

22. Cobrek's manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the clindamycin phosphate foam 1% described in ANDA No. 90-785 would also infringe, directly or indirectly, one or more claims of the '237 patent.

23. Perrigo's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 90-785 and its § 505(j)(2)(A)(viii)(IV) certification to the FDA also constitutes infringement of the '237 patent.

24. On information and belief, unless enjoined, Perrigo will, without authority, manufacture and/or import into the United States Cobrek's generic clindamycin phosphate foam 1% described in ANDA No. 90-785 and/or act as the exclusive distributor of the product within the United States upon Cobrek 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 clindamycin phosphate foam 1% described in ANDA No. 90-785 would infringe, directly or indirectly, one or more claims of the '237 patent.

26. Stiefel will be irreparably harmed by Cobrek and Perrigo's infringing activities unless those activities are enjoined by this Court. Stiefel does not have an adequate remedy at law.

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

28. Cobrek and Perrigo were aware of the existence of the '237 patent at the time of the submission of ANDA No. 90-785 and the § 505(j)(2)(A)(viii)(IV) assertions to the FDA and that that filing constituted infringement of the '237 patent. Their manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the clindamycin phosphate foam 1% described in ANDA No. 90-785 would constitute an act of willful infringement. This is therefore an exceptional case.

COUNT II- INFRINGEMENT OF U.S. PATENT NO. 7,374,747

29. Stiefel incorporates by reference the preceding averments set forth in paragraphs 1 through 28.

30. On May 20, 2008, the '747 patent, entitled "PHARMACEUTICAL FOAM," was duly and legally issued to Stiefel Research Australia Pty. Ltd. as assignee of the inventors named therein. A true and correct copy of the '747 patent is attached as Exhibit 2.

31. Cobrek has infringed one or more claims of the '747 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-785 seeking approval to market a generic version of a clindamycin phosphate foam 1% prior to the expiration of that patent.

32. Cobrek's manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the clindamycin phosphate foam 1% described in ANDA No. 90-785 would infringe, directly or indirectly, one or more claims of the '747 patent.

33. Perrigo's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 90-785 and its § 505(j)(2)(A)(viii)(IV) certification to the FDA also constitutes infringement of the '747 patent.

34. Perrigo's manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the clindamycin phosphate foam 1% described in ANDA No. 90-785 will infringe, directly or indirectly, one or more claims of the '747 patent.

35. Stiefel will be irreparably harmed by Cobrek and Perrigo's infringing activities unless those activities are enjoined by this Court. Stiefel does not have an adequate remedy at law.

36. Stiefel is entitled to the relief provided by 35 U.S.C. § 271(e)(4).

37. Cobrek and Perrigo were aware of the existence of the '747 patent at the time of the submission of ANDA No. 90-785 and the § 505(j)(2)(A)(viii)(IV) assertions to the FDA and that that filing constituted infringement of the '747 patent. Their manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the

clindamycin phosphate foam 1% described in ANDA No. 90-785 would constitute an act of willful infringement. This is therefore an exceptional case.

REQUEST FOR RELIEF

WHEREFORE, Stiefel respectfully requests that judgment be entered that:

(a) Cobrek and Perrigo have infringed one or more claims of the '237 and '747 patents;

(b) The manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the clindamycin phosphate foam 1% described in ANDA No. 90-785 would infringe one or more claims of the '237 and '747 patents;

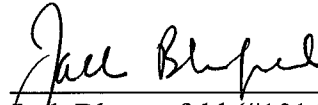
(c) The effective date of any approval of ANDA No. 90-785 for clindamycin phosphate foam 1% be not earlier than the expiration dates of the '237 and '747 patents;

(d) Preliminarily and permanently enjoining Cobrek and Perrigo, 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 Cobrek's clindamycin phosphate foam 1%;

(e) This is an exceptional case entitling Stiefel 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.

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