

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

STIEFEL LABORATORIES, INC.,)
)
Plaintiff,)
)
v.) C.A. No. _____
)
KV PHARMACEUTICAL COMPANY,)
)
Defendant.)

COMPLAINT

Plaintiff Stiefel Laboratories, Inc. (“Stiefel”), for its Complaint against Defendant KV Pharmaceutical Company (“KV”), alleges as follows:

THE PARTIES

1. Stiefel is a Delaware corporation having a principal place of business at 255 Alhambra Circle, Suite 1000, Coral Gables, Florida 33134.
2. On information and belief, KV is a corporation organized under the laws of the State of Delaware, having its principal place of business 2503 S. Hanley Road, St. Louis, Missouri 63144-2555.

JURISDICTION AND VENUE

3. This is a civil action for patent infringement arising under the patent laws of the United States.
4. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).
5. Venue in this judicial district is proper pursuant to 28 U.S.C. § 1391(b)-(c) and 1400(b).

6. This Court has personal jurisdiction over KV because it is a corporation organized under the laws of the State of Delaware.

PATENT INFRINGEMENT COUNT

7. On November 14, 1995, United States Patent No. 5,466,446 (“the ‘446 patent”), entitled TOPICAL COMPOSITIONS CONTAINING BENSOYL PEROXIDE AND CLINDAMYCIN AND METHOD OF USE THEREOF was duly and legally issued by the United States Patent and Trademark Office to Stiefel as assignee of the inventors named therein. A copy of the ‘446 patent is attached as Exhibit A.

8. Stiefel is the holder of a New Drug Application approved by the United States Food and Drug Administration (“FDA”) for Duac® Topical Gel, which is covered by the ‘446 patent.

9. KV has submitted to the FDA Abbreviated New Drug Application (“ANDA”) No. 90-979 pursuant to § 505(j) of the Federal Food, Drug and Cosmetic Act (“FFDCA”), 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, or sale of 1% clindamycin phosphate – 5% benzoyl peroxide topical gel. In its ANDA, KV included a certification pursuant to § 505(j)(2)(A)(vii)(IV) of the FFDCA alleging that the ‘446 patent is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of KV’s 1% clindamycin phosphate – 5% benzoyl peroxide topical gel product (a so-called “Paragraph IV Certification”).

10. Counsel for KV sent a letter dated April 10, 2009, notifying Stiefel that KV had filed an ANDA for 1% clindamycin phosphate – 5% benzoyl peroxide topical gel and was providing Stiefel with information pursuant to 21 U.S.C. § 355(j)(2)(B) (the “Notice Letter”). The Notice Letter also informed Stiefel that KV seeks approval to engage in the

commercial manufacture, use, or sale of its proposed 1% clindamycin phosphate – 5% benzoyl peroxide topical gel product prior to the expiration of the ‘446 patent. Stiefel received the Notice Letter on or about April 15, 2009.

11. Under 35 U.S.C. 271(e)(2)(A), KV has infringed one or more claims of the ‘446 patent by submitting to the FDA an ANDA seeking approval for the commercial manufacture, use or sale of 1% clindamycin phosphate – 5% benzoyl peroxide topical gel product prior to the expiration of the ‘446 patent.

12. Upon information and belief, KV intends to engage in the commercial manufacture, importation, use, sale or offer for sale of KV’s proposed 1% clindamycin phosphate – 5% benzoyl peroxide topical gel product upon receiving FDA approval to do so.

13. Unless enjoined by the Court, KV, upon approval of KV’s ANDA 90-979, will infringe the ‘446 patent by making, importing, using, selling and offering to sell KV’s proposed 1% clindamycin phosphate – 5% benzoyl peroxide topical gel product in the United States.

14. Stiefel will be substantially and irreparably harmed if KV’s infringement is not enjoined. Stiefel does not have an adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Stiefel respectfully requests that judgment be entered:

- (a) That KV has infringed one or more claims of the ‘446 patent;
- (b) That the manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the 1% clindamycin phosphate – 5% benzoyl peroxide topical gel product in ANDA No. 90-979 would infringe one or more claims of the ‘446 patent;

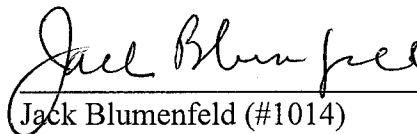
(c) That the effective date of any approval of ANDA No. 90-979 1% clindamycin phosphate – 5% benzoyl peroxide topical gel product be not earlier than the expiration date of the '446 patent;

(d) Preliminarily and permanently enjoining KV, its officers, agents, servants and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of KV's 1% clindamycin phosphate – 5% benzoyl peroxide topical gel product;

(e) That this is an exceptional case entitling Stiefel to an award of its reasonable attorneys' fees for bringing and prosecuting this action, 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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